IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BLUE CROSS AND BLUE SHIELD ASSOCIATION, IN ITS CAPACITY AS THE CARRIER FOR THE SERVICE BENEFIT PLAN, A/K/A THE "FEDERAL EMPLOYEE PROGRAM," A FEDERAL EMPLOYEE HEALTH BENEFITS ACT PLAN
225 North Michigan Ave.
Chicago, IL 60601

Plaintiff,

v.

CELGENE CORPORATION
86 Morris Avenue
Summit, New Jersey 07901

And

BRISTOL-MYERS SQUIBB COMPANY
430 E. 29th Street, 14 FL
New York, NY 10016

Defendants.

Case No:
Assigned to:
Assign. Date:
Description:

JURY TRIAL DEMANDED

TABLE OF CONTENTS

I. NATURE OF THE CASE 1

II. JURISDICTION AND VENUE 4

III. PARTIES…….. 5

IV. ECONOMIC BACKGROUND 7

V. THE REGULATORY BACKGROUND 9

a. The Hatch-Waxman Act and NDA Approval Process 9

b. The Hatch-Waxman Act and ANDA Approval Process 10

c. The Hatch-Waxman's Balancing Act 12

d. FDA can impose REMS 14

e. Brand Manufacturers Have Abused REMS to Block Generic Competition 15

f. State and Federal Governments Recognize the Anticompetitive Harm of REMS Abuse and Have Targeted REMS Abuse 16

g. Citizen Petitions 20

h. Patent Prosecution 22

VI. CELGENE'S REGULATORY HISTORY WITH THALOMID AND REVLIMID 22

VII. CELGENE'S ANTICOMPETITIVE SCHEME ILLEGALLY MONOPOLIZED THE MARKET FOR THALOMID AND REVLIMID 30

a. Celgene Unlawfully Manipulated FDA's REMS Program as a Pretextual Justification to Refuse Samples Needed to Prosecute ANDAs to Would-Be Competitors 30

i. Celgene's REMS Programs for Thalomid and Revlimid 31

ii. Celgene's REMS Programs are Post-Marketing Distribution Systems with No Legal or Practical Relation to Sales of Samples to Competitors 32

iii. Celgene Unlawfully Refused to Sell Samples to Would-Be Competitors 33

1. Celgene Refused to Sell Samples to Mylan 33

a. Mylan's Strong Safety Protocols Confirm and Illustrate the Pretextual and Unlawful Nature of Its Refusal to Sell Samples to Would-Be Competitors 43

2. Celgene Refused to Sell Samples to Exela 45

3. Celgene Refused to Sell Samples to Lannett 46

4. Celgene Refused to Sell Samples to Dr. Reddy's 50

5. Celgene Refused to Sell Samples to Teva 51

6. Celgene Refused to Sell Samples to Watson 51

7. Celgene Refused to Sell Samples to Sandoz 52

iv. Celgene Had No Legitimate Business Justification for Refusing Samples to Would-Be Competitors as Its Safety Concerns Were Pretextual 53

b. Celgene Induced Pharmacies and Ingredient Suppliers into Anticompetitive Exclusive Contracts to Prevent Generic Manufacturers from Accessing API 54

c. Celgene Fraudulently Obtained Patents for Thalomid and Revlimid and its Safety Distribution Protocols 58

i. Celgene Failed to Disclose Material Information on Patentability of the Drug Composition Patents 58

1. Celgene Tried to Extend its Monopoly by Filing Redundant Drug Composition Patents Based on Previously Ill-Gotten Patents 60

ii. Celgene Failed to Disclose Material Information on Patentability of The Distribution Method Patents 62

1. The Clorazil Patient Monitoring Service ("the CPMS") 65

2. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, 47(1):52-56 (1996) ("Honigfeld I") 66

3. Honigfeld, *et al*., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience

With the Clozaril National Registry," J. *Clin. Psychiatry* 59 (suppl 3): 3-7 (1998) ("Honigfeld II") 66

4. The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("the Guide")..... 67

5. The ACCUTANE® Pregnancy Prevention Program ("the PPP") 67

6. The Accutane PPP Package, a 1994 patent and prescriber information package for Accutane, distributed by Roche Pharmaceuticals ("the PPP Package") 68

7. A Centers for Disease Control public meeting entitled "Preventing Birth Defects Due to Thalidomide Exposure" and transcript from March 26, 1997 ("the CDC Meeting" and "the CDC Transcript") 68

8. Zeldis, *et al*., "S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("Zeldis")..... 69

9. The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting ("the CDER Meeting" and "the CDER Transcript") 70

10. The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" ("the NIH Meeting" and "the NIH Transcript") 72

11. The Distribution Method Patents are Unenforceable..... 73

12. Celgene Tried to Extend Its Monopoly by Filing Redundant Distribution Method Patents Based on its Previously Ill-Gotten Patents 75

iii. Celgene Attempted to Extend Its Monopoly by Filing Redundant Dosing Patents and Failed to Disclose Material Information on Patentability of the '745 Patent..... 77

d. Celgene Filed Baseless Citizen Petitions to Stymie Generic Approval..... 78

e. Celgene Serially Commenced "Sham" Patent Litigation and Struck Confidential Settlement Deals with the Generic Sponsors Which Likely Included Anti-

Competitive Reverse Payment Terms to Delay or Exclude Would-Be Competitors from Entering the Markets for Thalomid and Revlimid 80

i. Celgene's Sham Litigation Against Barr 81

ii. Celgene's Sham Litigation Against Lannett 83

iii. Celgene's Sham Litigation Against Natco, Arrow, and Watson 84

iv. Celgene's Sham Litigation Against Dr. Reddy's 87

v. Celgene's Sham Litigation Against Zydus 89

vi. Celgene's Sham Litigation Against Cipla 91

vii. Celgene's Sham Litigation Against Alvogen and Lotus 93

viii. Celgene's Sham Litigation Against Sun 95

ix. Celgene's Sham Litigation Against Hetero 96

x. Celgene's Sham Litigation Against Apotex 97

VIII. CELGENE INTENDED TO AND DID HARM COMPETITION 98

IX. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID CAUSED BCBSA TO PAY MORE THAN IT WOULD HAVE PAID IN AN UNMANIPULATED MARKET 100

X. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID AFFECTED INTERSTATE COMMERCE FOR THOSE DRUGS 101

XI. CELGENE MAINTAINED MONOPOLY MARKET POWER OVER THALOMID AND REVLIMID AND THEIR GENERIC FORMS 101

XII. ANTITRUST INJURY 103

XIII. CLAIMS FOR RELIEF 104

FIRST CLAIM FOR RELIEF
Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Sections 2 and 3 of the Sherman Act 104

SECOND CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law 105

THIRD CLAIM FOR RELIEF
Attempted Monopolization Under State Law 109

FOURTH CLAIM FOR RELIEF
Unfair and Deceptive Trade Practices Under State Law 112

FIFTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law 116

XIV. DEMAND FOR JUDGMENT 117

XV. JURY DEMAND 118

Plaintiff Blue Cross and Blue Shield Association, in its capacity as the carrier for the Service Benefit Plan, a/k/a the "Federal Employee Program," a Federal Employee Health Benefits Act Plan ("Plaintiff"), hereby sues Defendant Celgene Corporation ("Celgene") and Defendant Bristol-Myers Squibb Company ("Bristol-Myers Squibb"). Based on personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, Plaintiff alleges as follows:

I. NATURE OF THE CASE

1. "The most reviled drug of the 20th century is, incredibly, on its way to a second act. Thalidomide, used in the late 1950s and early 1960s as a sedative and anti-nausea medication, became the ultimate symbol of pharmacopoeia gone awry. When taken by pregnant women for morning sickness, it caused missing limb parts in the fetus . . . as well as organ damage and death. Fifty years after the drug's heyday, the fear it inspired haunts arguments about the safety and regulation of medications . . . That tragedy is a major reason the Food and Drug Administration has as much authority over new drugs as it does today."[1]

2. Enter Celgene, which granted new life to the failed wonder drug. In 1998, it obtained U.S. Food and Drug Administration ("FDA") approval to market Thalomid® (thalidomide) for a leprosy complication known as erythema nodosum leprosum ("ENL"). The fact that someone was able to salvage *something* positive from the thalidomide nightmare was, in many respects, remarkable.

3. In 2005, Celgene successfully developed a thalidomide analog, Revlimid® (lenalidomide), and obtained FDA approval to market it for a specific chromosomal variant of myelodysplastic syndromes ("MDS"). Celgene would go on to obtain FDA approvals for

[1] Amanda Schaffer, *Thalidomide's Comeback*, SLATE, Jan. 10, 2011, http://www.slate.com/articles/double_x/doublex/2011/01/thalidomides_comeback.html.

additional Revlimid indications, including for a subset of multiple myeloma ("MM") patients in 2006,[2] and later for a subset of mantle cell lymphoma ("MCL") patients in 2013.

4. However, unsatisfied with profits earned within the pharmaceutical legal and regulatory framework, Celgene commenced an anticompetitive scheme to illegally monopolize the market for Thalomid and Revlimid. Beginning in 2010, and only recently unearthed, Celgene constructed an impenetrable monopolistic fortress and engaged in a multipronged scheme to unlawfully maintain 100% share of the market for these two drugs by successfully interfering with competitors' efforts to develop and/or obtain FDA approval for generic versions of Thalomid and/or Revlimid at each progressive step of development. As part of this anticompetitive scheme, by information and belief, Plaintiff alleges that Celgene:

(1) manipulated the safety program designed to protect patients from thalidomide's and lenalidomide's teratogenic properties to refuse samples to would-be generic competitors;

(2) prevented pharmacies and ingredient suppliers from acting as alternative sources of samples for such would-be generic competitors;

(3) fraudulently obtained various patents from the U.S. Patent and Trademark Office ("USPTO") for Thalomid and Revlimid and their associated safety distribution protocols;

(4) filed baseless citizen petitions with FDA to stymie generic approvals; and

(5) serially commenced "sham" patent infringement lawsuits.

[2] Under FDA's orphan drug exclusivity program, 21 U.S.C. §§ 360aa-cc, FDA may not approve a generic equivalent for a specific indication or "rare disease" that a brand drug is FDA-approved to treat for a period of seven (7) years. MM is such a "rare disease." Therefore, until May 25, 2013, FDA could not approve a generic thalidomide for the treatment of MM. It could, nevertheless, approve generic thalidomide for the treatment of other indications. This is known as a "skinny label," which allows for market entry prior to the expiration of all exclusivities related to a drug.

5. Furthermore, in the rare instances where Celgene's efforts failed to prevent a would-be competitor from prosecuting an Abbreviated New Drug Application ("ANDA"), and FDA approval of an ANDA for a generic version of Thalomid or Revlimid became possible, Celgene entered into confidential settlements with its competitors that may have included anti-competitive "pay-for-delay" reverse payments. The federal government routinely has criticized – and challenged in court – the same sort of anticompetitive practices in which Celgene engages.[3]

6. In the last ten years, Celgene's anticompetitive scheme has allowed it to charge supracompetitive prices for Thalomid and Revlimid. In fact, Celgene has routinely increased its price either once or twice per year. In 2006, a month's supply of Revlimid cost $6,195.[4] In 2010, the price was about $8,000 for a one-month supply. Now, a twenty-eight-day supply of Revlimid costs patients and their health insurers as much as $20,000, and a twenty-eight-day supply of Thalomid costs them as much as $10,000. In 2016, Celgene's total revenue was $11.229 billion, of which $6.974 billion was from Revlimid and $152.1 million was from Thalomid. When Thalomid first entered the market, it cost approximately $6 per capsule. In 2014, its price soared to as much as $357 per capsule.

7. Celgene never saw a decrease in demand for the two drugs since Celgene illegally blocked and continues to block all generic alternatives.

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[3] *See, e.g.,* Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[4] Katherine Streeter, *How A Drugmaker Gamed The System to Keep Generic Competition Away* (May 17, 2018), https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

8. Celgene's illicit efforts with respect to Thalomid and Revlimid have been enormously profitable. Since 2006, Celgene has recorded $35.6 billion of Revlimid sales and $3.65 billion of Thalomid sales. Witness these drugs' respective net product sales:[5]

	2016	2015	2014	2013	2012	2011	2010	2009	2008	2007	2006
Revlimid	6974M	5800M	4980M	4280M	3770M	3210M	2470M	1706M	1325M	774M	321M
Thalomid	152M	185M	221M	245M	302M	339M	387M	437M	505M	447M	433M

9. Fast forward to 2019: Celgene's Revlimid sales for the third quarter were $2.7 billion, with its U.S. sales totaling $1.9 billion, and international sales at $868 million.[6] Revlimid is now the second-highest grossing drug worldwide,[7] and is projected to reach nearly $14 billion in worldwide sales by 2022.[8]

10. Celgene's anticompetitive tactics to block generic entry have caused Plaintiff to pay supracompetitive prices for these drugs in violation of states' antitrust and consumer protection, trade practices, and insurance fraud laws. BCBSA seeks civil damages it has incurred and injunctive relief.

II. JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1332, and 1337. BCBSA asserts federal claims for

[5] Net product sales figures drawn from Celgene's Annual Reports/Form 10-K filings for fiscal years ending 2007-2016.
[6] BusinessWire, *Celgene Reports Third Quarter 2019 Operating and Financial Results*, (Oct. 31, 2019), https://www.businesswire.com/news/home/20191031005259/en/Celgene-Reports-Quarter-2019-Operating-Financial-Results.
[7] Amy Brown, *EP Vantage 2017 Preview* (Dec. 2016), http://info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.
[8] Evaluate Ltd., *EvaluatePharma Orphan Drug Report 2017* (Feb. 2017), http://info.evaluategroup.com/rs/607-YGS-364/images/EPOD17.pdf. Not surprisingly, Revlimid was the top-selling "orphan drug" in the United States in 2016. *Id.* "An orphan drug is a pharmaceutical product aimed at rare diseases or disorders." *Id.*

injunctive relief and costs of suit, including reasonable attorneys' fees, against Defendants for the injuries sustained by BCBSA described herein by reason of the violations of Sections 2 and 3 of the Sherman Act, 15 U.S.C. §§ 2 and 3.

12. This Court has supplemental jurisdiction over BCBSA's pendent state law claims pursuant to 28 U.S.C. § 1367.

13. This Court has personal jurisdiction over Defendants because Defendants are present in the United States, do business in the United States, have registered agents in the United States, may be found in the United States, and are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

14. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §§ 1391(b) and (c). Defendant Celgene and Defendant Bristol-Myers Squibb transact business within this district, have agents and can be found in this district, and the relevant interstate trade and commerce is carried out, in substantial part, in this district.

III. PARTIES

15. Plaintiff Blue Cross Blue Shield Association is a national association of 36 independent, community-based and locally operated Blue Cross Blue Shield companies ("BCBS companies") with its headquarters in Chicago, Illinois. Blue Cross Blue Shield Association is incorporated under the laws of the state of Illinois as a not-for-profit corporation. Blue Cross Blue Shield Association owns and manages the Blue Cross and Blue Shield trademarks and names in more than 170 countries around the world. Blue Cross Blue Shield Association also grants licenses to independent companies to use the trademarks and names in exclusive geographic areas.

16. Plaintiff Blue Cross Blue Shield Association brings this action in its capacity ("BCBSA") as the carrier of the Service Benefit Plan a/k/a the Federal Employee Program

("FEP"), one of the Federal Employee Health Benefits Plans ("FEHBP"). Beginning in 1960, the Office of Personnel Management ("OPM") contracted with BCBSA under the Federal Employees Health Benefits Act ("FEHBA")[9] to establish the Government-wide FEHBP known as the Service Benefit Plan, also commonly known as the FEP. The FEP has the largest enrollment of any FEHBP. Pursuant to plan participation agreements between BCBSA and BCBS companies, BCBSA contracts with OPM for BCBS companies to underwrite and administer the FEP in their individual locales. However, BCBSA pays for drugs purchased by FEP enrollees through BCBSA's pharmacy benefits manager ("PBM"), including the drugs at issue in this case. Moreover, as the carrier under the contract with OPM and under the plan participation agreements, BCBSA has the sole authority to make decisions to bring actions on behalf of the FEP.

17. At all times relevant to the Complaint, BCBSA purchased Thalomid and Revlimid on behalf of the FEP for members through its PBM. As a result of Defendants' anticompetitive scheme, BCBSA paid supracompetitive prices for Thalomid and Revlimid, causing the FEP to be injured by the illegal conduct alleged herein. As defined above in ¶¶ 15-17, this Complaint refers to Plaintiff hereafter as "BCBSA".

18. Defendant Celgene Corporation is a drug manufacturer, incorporated in Delaware and headquartered at 86 Morris Avenue, Summit, New Jersey. Celgene manufactures and markets Thalomid and Revlimid.

[9] Congress enacted the Federal Employee Health Benefit Act ("FEHBA") in 1959 to provide health benefits for federal employees and retired federal employees and annuitants. 5 U.S.C. §§ 8901–8914. Accordingly, the FEHBA authorizes the Office of Personnel Management ("OPM") to contract with qualified health benefits carriers to provide health benefits under a federal government procurement contract. 5 U.S.C. §§ 8902(a).

19. Defendant Bristol-Myers Squibb Company wholly owns Defendant Celgene Corporation as its subsidiary and has since Bristol-Myers Squibb acquired Celgene pursuant to a January 2, 2019 Merger Agreement. Bristol-Myers Squibb is a biopharmaceutical drug company incorporated under the laws of Delaware with its principal executive offices located at 430 E. 29th Street, 14 FL, New York, NY 10016. Bristol-Myers Squibb is a publicly traded corporation registered on the New York Stock Exchange under the symbol "BMY."

IV. ECONOMIC BACKGROUND

20. Due to laws that regulate marketing/selling, prescribing, and filling prescription drugs, the United States is a fertile venue ripe for illegal anticompetitive exploitation by drug manufacturers who seek to profit from product monopolies.

21. For most consumer products, the person responsible for paying for them is also the person selecting them. The pharmaceutical marketplace departs from this norm.

22. Prescription drugs may only be dispensed pursuant to a doctor's prescription, and a licensed pharmacist may dispense only the brand-name drug named in the prescription or its AB-rated,[10] FDA-approved generic equivalent.[11]

23. In most instances, the patient and his health insurer pay for the prescription drug that a doctor has prescribed. Therefore, the doctor's prescription defines the relevant product market, because it limits the patients' (and pharmacist's) choice to the drug named therein.

24. When there is no generic competition for a brand-name drug, the brand manufacturer can set and maintain prices without losing market share. The ability to do this is the result of the brand-name drug company's monopoly power over the market for that drug in

[10] FDA grants an AB-rating to generic drugs that meet necessary bioequivalence requirements.
[11] In many states, pharmacists must substitute an AB-rated generic for a brand-name drug without seeking permission from the prescribing doctor.

both its brand-name and generic form. When an AB-rated generic is available, price is reintroduced to the product selection decision at the pharmacy counter, and the disconnect between choice and payment is lessened, disabling the brand manufacturer from exploiting that disconnect. Generic introduction restores normal competitive pressures.

25. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a brand-name drug predictably decrease, sometimes as much as by 90%, because of price competition among generic manufacturers.[12] FDA reports that, in 2010, the use of FDA-approved generics saved $158 billion, or $3 billion per week, and that one year after entry, a generic drug takes over 90% of the corresponding brand-name drug's sales at 15% of the price. Generic drug entry, therefore, is a huge threat to the continued profitability of a branded drug.

26. As the price gap between the brand-name drug and its corresponding generic drug widens, the former's sale volume shrinks. Price is the only material difference between a brand-name drug and its AB-rated generic equivalent.

27. For every rung in the prescription drug ladder, except for the brand-name drug manufacturer, there is a financial benefit to choosing the generic drug. Pharmacies normally earn a higher markup on generic drugs because of pricing structure and federal reimbursement rules

[12] *See*, *e.g.*, Jon Leibowitz, *"Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform* (June 23, 2009), http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements-pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf.

and private health insurers typically offer incentives to pharmacies and members to fill prescriptions with generics such as lower copays for generic drugs than for brand-name drugs.

28. Generic competition enables third party payers like BCBSA to purchase a generic version of a brand-name drug at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no generic drug which competes effectively with the brand-name drug, and therefore, the brand-name manufacturer can charge supracompetitive prices without losing sales. Given their acute knowledge of the effects of generic entry into a market, brand-name manufacturers like Celgene have a strong incentive to delay such entry through various means, including by entering illegal reverse "pay for delay" settlement agreements and serially filing frivolous patent infringement lawsuits.

V. THE REGULATORY BACKGROUND

a. The Hatch-Waxman Act and NDA Approval Process

29. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), a manufacturer that creates a new, pioneer drug must obtain FDA approval to sell the drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug and identify any patents claiming the drug. 21 U.S.C. § 355(b).

30. When FDA approves a brand-name manufacturer's NDA, it lists in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents which, according to the information supplied to FDA by the brand-name manufacturer: (1) claim the approved drug or its approved uses; and (2) for which a "claim

of patent infringement could reasonably be asserted if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug."[13]

31. FDA does not investigate the patents or verify the NDA sponsor's representations for accuracy or trustworthiness prior to listing patents in the Orange Book. Listing such a patent is a pure ministerial act.

32. Once a brand manufacturer lists a patent in the Orange Book, it puts potential generic competitors on notice that the brand considers the patent to cover its drug.

b. The Hatch-Waxman Act and ANDA Approval Process

33. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman Act ("Hatch-Waxman"). Congress' principal intent was for Hatch-Waxman to simplify and reduce the regulatory hurdles for prospective generic manufacturers, by replacing the lengthy and costly NDA approval process with an expedited ANDA review process.[14] Under Hatch-Waxman, an ANDA applicant may rely on the safety and efficacy findings of the NDA for the referenced brand-name drug if the ANDA demonstrates the proposed generic drug is therapeutically equivalent and "bioequivalent," ("BE") *i.e.*, it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug, and is absorbed at the same rate, and to the same extent, as the brand-name drug. For ANDAs that pass this test, FDA assigns an "AB" rating to the generic drug.

34. BE is generally demonstrated via studies in which the proposed generic is compared to the Reference Listed Drug ("RLD," which is, in this instance, the brand-name drug)

[13] 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).
[14] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

in either *in vivo* or *in vitro* studies.[15] These studies require the ANDA applicant to have access to sufficient samples of the RLD to conduct the necessary comparisons. Without RLD samples, it is impossible to complete and file an ANDA application.

35. FDA illuminates the issue:

> To obtain approval for a generic drug, the generic company needs to show, among other things, that its version of the product is bioequivalent to the RLD [i.e. the brand drug, or reference listed drug]. This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain samples of the RLD used in testing after a study is complete. To conduct these kinds of bioequivalence studies, the generic company needs to obtain samples (generally between 1,500 and 5,000 units) of the RLD.[16]

36. Only samples of the RLD approved by FDA and marketed in the United States may be used for BE testing purposes. In the ordinary course, a prospective ANDA sponsor obtains samples by buying them, at market price, from a drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from manufacturers for the purpose of re-selling them to pharmacies or other entities. Generic companies are authorized to buy prescription drugs from distributors for BE testing purposes.

37. Celgene's own former senior vice president of global regulatory affairs, drug safety, risk management, and quality assurance Graham Burton testified that Celgene is the only source from which a generic company could obtain Thalomid or Revlimid for purposes of BE testing.[17]

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[15] *In vivo* studies are studies conducted on live subjects. *In vitro* studies are conducted in a laboratory.

[16] FDA, *Reference Listed Drug (RLD) Access Inquiries*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Feb. 26, 2019).

[17] Exhibit to Brief in Opposition to Motion for Summary Judgment, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02095-ES-MAH (D.N.J. Mar. 20, 2018) ("MSJ Opp."), Dkt. No. 285-15 at 69-70.

c. The Hatch-Waxman's Balancing Act

38. As a counterbalance to Hatch-Waxman's simplified ANDA process, Hatch-Waxman also provides brand manufacturers with the ability—merely by filing a patent infringement lawsuit—to easily obtain what is essentially a preliminary injunction, in the form of an automatic stay of up to thirty months, of FDA's ability to approve a generic manufacturer's ANDA.

39. To obtain FDA approval of an ANDA, the generic manufacturer must certify that it will infringe no patent listed in the Orange Book claiming the brand drug, because either:

a. No patent for the brand-name drug has been filed with FDA (a "Paragraph I Certification");
b. The patent for the brand-name drug has expired (a "Paragraph II Certification");
c. The patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
d. The patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV Certification").[18]

40. When a generic manufacturer files a Paragraph IV Certification, it must notify the brand manufacturer and patent owner. The ANDA filing itself becomes an artificial act of patent infringement, entitling the patent holder to sue for injunctive relief, according to Hatch-Waxman.

41. If the patent holder sues the ANDA filer within forty-five days of receiving the Paragraph IV Certification, Hatch-Waxman prevents FDA from granting final approval to the ANDA until the earlier of (a) thirty months after the lawsuit is commenced, or (b) the court presiding over the patent infringement action rules that the patent is invalid or not infringed by the ANDA.[19] It is almost always the case that the thirty month period expires before the court rules, resulting in a 30-month statutory stay.

[18] 21 U.S.C. § 355(g)(2)(A)(vii).
[19] 21 U.S.C. § 355(j)(5)(B)(iii).

42. However, during the 30-month stay, FDA may grant "tentative approval" to an ANDA applicant if the agency determines that the ANDA would qualify for final approval, but for the 30-month stay.

43. Hatch-Waxman also grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant ("first filer") to file a substantially complete ANDA. During the 180-day exclusivity period (measured from the first commercial marketing of the generic drug or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed[20]), the first ANDA filer enjoys 180 days of freedom from competition from other generic versions of the drug, and during that period can capture almost all of the market for the drug while selling the generic for a higher price than the market will support once additional generics enter the market.

44. Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA").[21] The MMA creates numerous conditions under which a first filer forfeits its 180-day exclusivity, thereby allowing other ANDA filers to enter the market. For example, forfeiture occurs if the first filer fails to obtain tentative approval within thirty months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

45. Under the "Agreement with another applicant" provision, the first filer will forfeit its exclusivity if it "enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV certification] …."[22]

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[20] 21 U.S.C. § 355(j)(5)(B)(iv)); *see also* 21 C.F.R. § 314.107(c)(1)).
[21] Public Law 108-173; 21 U.S.C. A. § 355(j)(5)(D).
[22] 21 U.S.C. A. § 355(j)(5)(D)(i)(V).

46. Under the "failure to market" provision, a first filer forfeits its 180-day exclusivity if it fails to market its generic drug by the *later of*:

> (a) *the earlier* of the date that is
> (1) 75 days after receiving final FDA approval; or
> (2) 30 months after the date it submitted its ANDA; or
> (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred
> (1) a final decision of invalidity or non-infringement;
> (2) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or
> (3) the NDA holder delists the patent from the Orange Book.[23]

47. Branded-manufacturers and first filers can structure an agreement to circumvent the above provisions and keep the 180-day exclusivity in place by, among other things, settling their litigation before a final judgment of invalidity or non-infringement can be entered, or by seeking a consent judgment that does not include a finding that all the patents for which the first filer submitted a Paragraph IV Certification were invalid or not infringed. Consequently, a subsequent ANDA filer can fight this only by itself obtaining a judgment that all patents for which the first filer filed a Paragraph IV Certification are invalid or not infringed, thereby triggering forfeiture of the first filer's 180-day exclusivity rights.

d. FDA can impose REMS

48. Since at least the 1960s, FDA has examined and implemented various methods for managing risks related to pharmaceutical products. Methods have included disclosure and labelling requirements. The Controlled Substances Act of 1970 saw the regulation of manufacturers, prescribers, dispensers, and labels, and permitted FDA to require warnings on packages.[24]

[23] 21 U.S.C.A. § 355(j)(5)(D)(i)(I).
[24] 21 U.S.C. § 801 *et seq.* (2002).

49. In the 1990s, FDA began to work with manufacturers to develop risk management programs for drugs with dangerous side effects. Then, in the 2000s, FDA established Risk Minimization Action Plans ("RiskMAPs"), in which manufacturers voluntarily instituted risk minimizing plans.

50. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which codified the Risk Evaluation and Mitigation Strategies ("REMS") to be implemented with respect to certain pharmaceutical products "that have already been approved" and directed the Secretary of Health and Human Services ("HHS") to establish an active post-market drug surveillance infrastructure.[25]

51. A REMS can include, *inter alia*, a medication guide, patient package inserts, and/or restrictions on the distribution of the drug.

52. Since their enactment in 2007, REMS have been increasingly common in FDA's approval process; roughly 40% of new drugs have REMS programs.

53. REMS are intended to give FDA authority to condition drug approval on the implementation of a program designed to address serious risks associated with particular pharmaceutical products. The intention is not to make drugs, or drug samples, less available. In fact, § 505-1(f)(8) of the FDAAA explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. The FDAAA does not prohibit the sale of REMS-subject drugs to generic manufacturers that will use those drugs in controlled BE testing, nor does it give an NDA holder the right to interfere with a competitors' ability to purchase necessary drug samples.

e. Brand Manufacturers Have Abused REMS to Block Generic Competition

[25] 21 U.S.C. § 355-1(f)(8).

54. Competition from generics dramatically reduces a brand manufacturer's profits as prices erode and the brand loses market share. Brand manufacturers are therefore highly motivated to delay or block generic entry by extending their monopoly beyond its legal limits. Brand manufacturers have come to do this through, *inter alia*, abusing and "gaming" REMS programs.

55. In 2016, Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research ("CDER"), testified that brand companies often use REMS programs "as an excuse to not give the drug to the generics so they can compare it to their drug." This behavior, she noted, causes "barriers and delays in getting generics on the market."[26]

f. State and Federal Governments Recognize the Anticompetitive Harm of REMS Abuse and Have Targeted REMS Abuse

56. REMS abuse is anticompetitive behavior that unlawfully excludes market entry by generic competitors. REMS abuse has caused real and substantial harm to the American public as generics drugs' resulting inability to enter the market has increased U.S. healthcare costs by more than $5 billion annually.[27]

57. To combat this harm, Congress enacted material portions of the "Creating and Restoring Equal Access to Equivalent Samples Act of 2016" (commonly known as "CREATES") on December 20, 2019.[28] CREATES establishes a standalone private right of action for qualifying developers of generic drugs to sue branded drug manufacturers, like

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[26] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

[27] Association for Accessible Medicines, *Increase Competition & Access – Support CREATES Act*, https://accessiblemeds.org/campaign/increase-competition-and-access-rems (last visited Feb. 26, 2019).

[28] Material portions of CREATES were incorporated into the Further Consolidated Appropriations Act, 2020, Pub. L. 116-94.

Celgene, that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms."[29] Available remedies include immediate provision of sufficient quantities of samples of the drug on commercially reasonable terms, attorney's fees and costs, and civil fines "sufficient to deter" a defendant brand manufacturer from withholding samples to other companies developing generics in the future.[30]

58. Reflecting the astounding financial incentives brand manufacturers have to engage in REMS abuse, the Pharmaceutical Researchers and Manufacturers of America, comprised of branded pharmaceutical drug manufacturers, spent an extraordinary amount of lobbying funds opposing CREATES, including $10 million in the first quarter of 2018 alone.[31]

59. The passage of the bipartisan bill confirms the anticompetitive harm inflicted by brand manufacturers, like Celgene, who abuse the REMS process to unlawfully monopolize the market for a drug by excluding generic competition beyond the period and scope afforded by a lawfully obtained patent.[32] CREATES is designed to thwart monopolization schemes like Celgene's by expeditiously delivering needed samples to companies developing generic drugs.

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[29] 21 U.S.C. § 355-2(b)(1).
[30] 21 U.S.C. § 355-2(b)(4).
[31] *See* Jessie Hellman, *PhRMA Spends Record Amount on Lobbying Amid Drug Pricing Fights*, THE HILL, Apr. 20, 2018, https://thehill.com/policy/healthcare/384176-phrma-spends-record-amount-on-lobbying-amid-drug-pricing-fights.
[32] Senator Patrick Leahy's (D-VT) committee comments echoed Celgene's conduct here alleged: "The first delay tactic addressed by the CREATES Act involves withholding of drug samples that generic manufacturers need to gain regulatory approval. Federal law requires generic competitors to prove that their low-cost alternative is equally safe and effective as the brand-name drug with which they wish to compete. Unfortunately, some brand-name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition." Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Statement of Senator Patrick Leahy (June 21, 2016), https://www.judiciary.senate.gov/download/06-21-16-leahy-statement-2.

However, Congress's passage of an additional tool to expose pretextual denials does not alter the unambiguously unlawful nature of REMS abuse and monopolization schemes like Celgene's. Rather, CREATES acknowledges the rampant abuse of the REMS system by manufacturers like Celgene and seeks to mitigate the harm that such unlawful behavior has and continues to impose. As such, CREATES is a confirmation of the central unlawfulness of REMS abuse and an attempt to pragmatically address it.

60. The need to address REMS abuse through CREATES was not a function of any ambiguity in the law, but rather an acknowledgement that a unified chorus of regulatory officials and legislators had failed to deter REMS abuse despite years of denunciations, the issuing of nonbinding comments, investigations, and public shaming, which often singled out Celgene's REMS abuse in connection with Thalomid and Revlimid. For instance, over the prior decade, FDA: issued official clarifications that REMS programs should not be used for anticompetitive reasons;[33] issued safety determination letters to brand companies that confirmed that FDA would not consider providing samples of the RLD for generic BE testing to be a violation of REMS;[34]

[33] *See* Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research).

[34] *See e.g.*, FDA Center for Drug Evaluation and Research, *Draft Guidance: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD* (Dec. 2014), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425662.pdf ("2014 Draft Guidance") ("In the interest of facilitating prospective generic applicants' access to RLD supplies to conduct the testing necessary to support ANDA approval, FDA has, on request, reviewed the [generic's] BE study protocols proposed by prospective ANDA applicants to assess whether they provide safety protections comparable to those in the applicable REMS ETASU. When the Agency has determined that comparable protections existed, FDA has issued letters to the RLD sponsors stating so and indicating that FDA would not consider it to be a violation of the REMS for the RLD sponsor to provide drug product to the prospective ANDA applicant.").

regularly testified about REMS abuse before Congress;[35] and took the extraordinary step of regularly publishing a list of brand-name drugs that had been the target of complaints that their NDA-holder (or manufacturer) is denying access to samples of RLDs when generic companies seek to buy them.[36] The Connecticut Attorney General's office initiated an investigation into Celgene's alleged REMS abuse, and wrote in January 2013 that Celgene's responses to its REMS abuse inquiry "ha[ve] raised serious concerns in my office that, notwithstanding its claims to the contrary, Celgene is not truly willing to sell Revlimid samples in a manner that would allow the BE testing necessary for a competitor to submit an ANDA….Celgene's current actions raise the specter that the discussions have been nothing but an artifice to continue to allow Celgene to delay the development of a generic alternative to Revlimid."[37] Additionally, the Federal Trade Commission ("FTC") FTC began to regularly testify before Congress concerning

[35] *See e.g.*, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition* (May 17, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm.

[36] Unsurprisingly, Celgene is listed thrice on the list, as FDA received numerous access inquiries for Celgene's Thalomid, Revlimid, and a third drug not subject to this Complaint, Pomalyst (pomalidomide). The list documents that FDA received ten inquiries related to Thalomid, thirteen inquiries related to Revlimid, and eight inquiries related to Pomalyst. FDA issued at least four safety letters for Revlimid, including on July 21, 2012, May 19, 2014, February 22, 2017, and August 15, 2017. FDA issued safety letters for Thalomid on December 12, 2007, and January 17, 2008.

[37] *See e.g.*, Exhibit to MSJ Opp., Doc. No. 285-21 ("[d]espite clear guidance from both Congress and FDA that drug firms should not use REMS programs to block or delay generic or biosimilar competition, complaints about abuse of the regulatory process persist . . . One study estimates that Americans have lost $5.4 billion in annual savings due to delays in accessing drug samples caused by REMS misuse and other non-FDA mandated restricted distribution programs.").

REMS abuse[38] and submitted statements to the Department of Health and Human Services ("DHHS") urging action.[39]

g. Citizen Petitions

61. Section 505(j) of the FDCA creates a mechanism that allows a person to file a petition with FDA requesting that the agency take, or refrain from taking, any form of administrative action. This is known as a "citizen petition."

62. A citizen petition allows a citizen to notify FDA of its genuine concerns about safety, scientific, or legal issues regarding a product at any time before or after it enters the market.

63. Pursuant to FDA regulations, FDA must respond to a citizen petition within 180 days of receipt with a grant in whole or in part, or a denial of the petition. The FDA can provide a tentative response with an estimate on a time for a full response.

64. Gary Buehler, R.Ph., former Director of the Office of Generic Drugs ("OGD") at CDER, noted that of forty-two citizen petitions raising issues about the approvability of generic

[38] *Antitrust Concerns and FDA Approval Process*, Prepared Statement Markus H. Heier, Bureau of Competition, Federal Trade Commission before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Judiciary Committee, United States House of Representatives, Washington, D.C. (July 27, 2017), https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda; *Oversight of the Enforcement of the Antitrust Laws,* Prepared Statement of the Federal Trade Commission before the Subcommittee on Antitrust, Competition Policy and Consumers Rights, Judiciary Committee, U.S. Senate (Oct. 3, 2018).

[39] *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, Statement of the Federal Trade Commission to the U.S. Department of Health and Human Services (July 16, 2018), *available at* www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-humanservices-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf. ("[b]y improperly blocking the product developer from obtaining samples, the branded manufacturer can potentially delay or indefinitely block generic or biosimilar competition to its product, thereby reducing the competition that Congress specifically sought to facilitate via the Hatch-Waxman Act . . . .").

products, "very few . . . have presented data or analysis that significantly altered FDA's policies." Despite this, it is standard practice for FDA to withhold ANDA approval until it has completed its research into and response to a citizen petition.

65. Responding to a citizen petition strains FDA's limited resources. Regardless of how frivolous a petition may be, FDA must expend considerable resources researching the petition's scientific, medical, legal, and economic issues, and delaying ANDA approval, even if a petition is later found to be baseless.

66. Frivolous petitions sponsored by branded manufacturers have become an increasingly common tactic to delay generic competition.

67. In many cases, citizen petitions have been filed relating to ANDAs that have been pending for over a year, long after the brand manufacturer received notice of the ANDA filing. In these cases, the petition delays the ANDA approval while FDA evaluates the citizen petition. In most cases, there is no legitimate reason for the brand manufacturer's delay in filing the citizen petition.

68. FDA has acknowledged manipulation of the citizen petition review process. Former FDA Chief Counsel Sheldon Bradshaw recognized that during his tenure he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality of scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

h. Patent Prosecution

69. Filing a patent application is an *ex parte* process for which the law imposes a duty of good faith, candor, and disclosure on the filing party.[40] This duty requires the filer, including his or her agents, attorneys, or anyone else involved in the prosecution, to disclose all material information on the patentability of the claims.

70. An applicant's intentional withholding of information known to be material to patentability with the intent to deceive the USPTO constitutes inequitable conduct and renders a patent unenforceable.

71. The existence of prior art is material to patentability.[41] Prior art means that "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public" or "the claimed invention was described in a patent issued under section 151, or in an application for a patent published or deemed published under section 122(b)...."[42]

VI. CELGENE'S REGULATORY HISTORY WITH THALOMID AND REVLIMID

72. In the mid-20th Century, thalidomide was marketed as a sleeping pill and anti-morning sickness pill for pregnant women. Devastatingly, when consumed by pregnant women, thalidomide caused life-threatening fetal deformities and birth defects. Adverse effects also included nerve damage.

73. Thalidomide was thereafter banned worldwide. The U.S. ban was in place until July 16, 1998, when FDA approved Celgene's December 20, 1996 NDA 20-785 for Thalomid, its branded version of thalidomide. FDA approved Thalomid only as a treatment for ENL, a form

[40] *See* 37 C.F.R. § 1.56; Manual of Patent Examining Procedure § 2000.
[41] *See* 35 U.S.C. § 102.
[42] 35 U.S.C. § 102(a)(1)-(2).

of leprosy.[43] To mitigate fetal exposure to the drug, FDA conditioned its Thalomid approval on Celgene's use of the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S.") distribution program, in which patients were required to review educational materials, register with the program, and agree to program restrictions. FDA noted in its Thalomid NDA approval "[t]hat current restrictions strike a balance between the need to prevent fetal exposure to the drug and the need to make the drug available without extraordinary burdens on patients and prescribers."

74. After FDA codified its REMS distribution program, FDA approved Celgene's supplemental NDA containing a proposed REMS program for Thalomid on August 3, 2010.

75. Celgene filed, prosecuted, and listed in the Orange Book, one patent for the Composition of Matter for Thalomid: the '012 Patent, which was first filed with the USPTO in June 2003. Celgene filed, prosecuted and listed, a total of fourteen patents in relation to the S.T.E.P.S. and/or REMS programs for controlling Thalomid, and later Revlimid, distribution: the '501 Patent, the '976 Patent, the '432 Patent, the '984 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '399 Patent, the '018 Patent, the '566 Patent, the '886 Patent, and the '531 Patent, all of which were filed with the USPTO between August 1998 and August 2012.

76. Revlimid is an immunomodulatory drug that works against cancer cells by affecting the immune system. It is a thalidomide analogue manufactured and marketed by Celgene. On April 7, 2005, Celgene submitted NDA 21-880 to FDA, which provides for the use of Revlimid to treat patients with transfusion dependent anemia due to low or intermediate-1 risk

[43] Thalomid was later approved in 2006 to treat Multiple Myeloma ("MM"), subject again to Celgene's restricted distribution system.

myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities. On December 27, 2005, FDA approved Revlimid for this indication. FDA granted Celgene market exclusivity for Revlimid as a new chemical entity ("NCE") until December 27, 2010.

77. Revlimid is subject to a REMS distribution program, RevAssist. The primary goal of the RevAssist program is to prevent fetal exposure to Revlimid. FDA noted in its December 27, 2005 letter to Celgene that RevAssist is "an important part of the post-marketing risk management for Revlimid®."

78. In addition to the patents listed in the Orange Book, Celgene was issued numerous additional patents related to thalidomide and its analogs. According to 21 U.S.C. § 355(b)(1), NDA applicants must include any patent numbers and their expiration dates which either claims the drug for which the sponsor seeks approval or a method of using such drug. Despite not listing these additional patents in the Orange Book, Celgene has made frivolous infringement claims for these patents in response to ANDAs for lenalidomide, as discussed below.[44]

79. Celgene also filed, prosecuted, and listed in FDA Orange Book three patents for the Composition of Matter for Revlimid: the '517 Patent, which was first filed with the USPTO in July 1996, and the two polymorph patents, the '800 Patent and the '217 Patent, first filed with the USPTO in September 2004 and December 2008, respectively (the "Polymorph Patents"). Celgene filed, prosecuted, and listed several patents in relation to the RevAssist program for controlling Revlimid distribution: the '501 Patent, the '976 Patent, the '432 Patent, the '763

[44] Celgene also filed and prosecuted several additional patents that it did not list in the Orange Book. They are Patent Nos. 6,555,554 (the "'554 patent"), 7,119,106 (the "'106 patent"), 6,281,230 (the "'230 patent"), 6,767,326 (the "'326 patent"), 7,977,357 (the "'357 patent"), 8,193,219 (the "'219 patent") and 8,431,598 (the "'598 patent").

Patent, the ’188 Patent, the ’720 Patent, the ’977 Patent, the ’784 Patent, the ’886 Patent, and the ’531 Patent, all of which were filed with the USPTO between August 1998 and August 2012. Celgene filed, prosecuted, and listed ten patents related to the dosage and methods of treatment for Revlimid: the ’740 Patent, the ’569 Patent, the ’363 Patent, the ’929 Patent, the ’717 Patent, the ’095 Patent, the ’120 Patent, the ’498 Patent, the ’621 Patent, and the ’622 Patent, all filed with the USPTO between April 2003 and September 2014. In 2006, Celgene filed yet another patent, the ‘745 Patent in furtherance of its pattern of erecting an impenetrable “patent fortress” around its Thalomid and Revlimid monopolies.

80. Witness below a chart of Celgene’s patent protection web:

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drugs
Composition of Matter						
’517 Patent	5,635,517	24-Jul-96	3-Jun-97	4-Oct-19	Method of reducing TNF.alpha. levels with amino substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines	Revlimid
’012 Patent	7,230,012	30-Jun-03	12-Jun-07	9-Dec-23	Pharmaceutical compositions and dosage forms of thalidomide	Thalomid
Polymorph						
’800 Patent	7,465,800	3-Sep-04	16-Dec-08	27-Apr-27	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid

’217 Patent	7,855,217	15-Dec-08	21-Dec-10	24-Nov-24	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid

REMS						
’501 Patent	6,045,501	28-Aug-98	4-Apr-00	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’976 Patent	6,561,976	26-Sep-01	13-May-03	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’432 Patent	6,908,432	22-Jan-04	21-Jun-05	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’984 Patent	7,874,984	12-Apr-05	25-Jan-11	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid

’763 Patent	8,204,763	13-Dec-10	19-Jun-12	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’188 Patent	8,589,188	17-May-12	19-Nov-13	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’720 Patent	6,315,720	23-Oct-00	13-Nov-01	23-Oct-20	Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug	Thalomid Revlimid (Pomalyst)
’977 Patent	6,561,977	27-Sep-01	13-May-03	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
’784 Patent	6,755,784	7-Mar-03	29-Jun-04	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)

’399 Patent	6,869,399	22-Jan-04	22-Mar-05	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’018 Patent	7,141,018	3-Jan-05	28-Nov-06	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’566 Patent	7,959,566	19-May-06	14-Jun-11	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’886 Patent	8,315,886	13-Dec-10	20-Nov-12	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
’531 Patent	8,626,531	22-Aug-12	7-Jan-14	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
Dosing						

’740 Patent	7,189,740	11-Apr-03	13-Mar-07	11-Apr-23	Methods of using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the treatment and management of myelodysplastic syndromes	Revlimid
’569 Patent	7,968,569	15-May-03	28-Jun-11	7-Oct-23	Methods for treatment of multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’363 Patent	7,468,363	8-Apr-05	23-Dec-08	7-Oct-23	Methods for treatment of cancers using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’929 Patent	8,741,929	19-Nov-09	3-Jun-14	8-Mar-28	Methods using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for treatment of mantle cell lymphomas	Revlimid
’717 Patent	8,404,717	24-Mar-11	26-Mar-13	11-Apr-23	Methods of treating myelodysplastic syndromes using lenalidomide	Revlimid
’095 Patent	8,648,095	5-Jun-12	11-Feb-14	15-May-23	Methods for treating multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione in combination with proteasome inhibitor	Revlimid

’120 Patent	9,056,120	13-Mar-13	16-Jun-15	11-Apr-23	Methods of treating myelodysplastic syndromes with a combination therapy using lenalidomide and azacitidine	Revlimid
’498 Patent	8,530,498	8-Apr-13	10-Sep-13	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione	Revlimid
’621 Patent	9,101,621	17-Apr-14	11-Aug-15	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione after stem cell transplantation	Revlimid
’622 Patent	9,101,622	10-Sep-14	11-Aug-15	15-May-23	Methods for treating newly diagnosed multiple myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione in combination with dexamethasone	Revlimid
’745 Patent	7,435,745	26-Apr-06	14-Oct-08	31-Jul-19 (Estimate)	Methods and compositions for inhibition of angiogenesis	Thalomid (Not listed in Orange Book)

VII. CELGENE’S ANTICOMPETITIVE SCHEME ILLEGALLY MONOPOLIZED THE MARKET FOR THALOMID AND REVLIMID

a. Celgene Manipulated FDA’s REMS Program as a Pretextual Justification to Refuse Samples Needed to Prosecute ANDAs to Would-Be Competitors

81. Central to Celgene's multi-faceted and decades long scheme to unlawfully monopolize the markets for Thalomid and Revlimid was its REMS abuse. Celgene used its associated REMS distribution programs as a pretext to delay and ultimately refuse to sell samples of Thalomid and Revlimid to competitors that were needed to develop ANDAs, despite exhaustive cautionary measures taken by competitors and comprehensive assurances by FDA. These measures reveal Celgene's claimed business justifications as entirely pretextual.

i. Celgene's REMS Programs for Thalomid and Revlimid

82. Both Thalomid and Revlimid are subject to REMS distribution programs that require healthcare providers and pharmacies to be certified in the S.T.E.P.S. or RevAssist programs, respectively, and patients to be enrolled in these programs. Prescribers and pharmacists must complete registration forms. Women of childbearing age must take a pregnancy test twenty-four hours prior to starting a course of Thalomid or Revlimid and at least every four weeks during their course of treatment. Prescribers must provide patients with contraception and emergency contraception counseling with each new prescription. For every new patient, prescribers must submit to Celgene a signed Patient-Physician Agreement Form that identifies the patient's risk category. The prescriber then receives a letter confirming the patients' enrollment and the patient and prescriber receive an authorization number which is to be written on the prescription. The pharmacy must verify that each prescription has an authorization number that is valid for seven days. The pharmacy must then call Celgene, obtain a confirmation number, and write this number on the prescription. The prescription is then filled within twenty-four hours. No more than a twenty-eight-day supply may be dispensed at one time.

83. RevAssist operates through specialty pharmacies. The S.T.E.P.S. program initially operated in all pharmacies. In 2006, Celgene narrowed the S.T.E.P.S. program to be

exclusively operated through specialty pharmacies. Alexis Tosti, Celgene's Market Research Analyst, noted that this move would "be a hurdle for generic companies," and that "[r]estricted distribution is more likely to keep thalidomide out of the hands of generic companies who need product to test against the generic being developed," in internal company emails in 2006.[45]

84. The first key to Celgene's monopolistic anticompetitive scheme was to prevent generic manufacturers from obtaining the necessary samples of Thalomid and Revlimid to perform the BE testing needed to file an ANDA.

85. Celgene abused its REMS program as a pretextual justification for withholding Thalomid and Revlimid samples from generic competitors. Among the manufacturers that Celgene refused to supply are Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, Exela Pharmsci, Inc. ("Exela") in 2006, Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009, Watson Laboratories, Inc ("Watson") in 2009, Teva Pharmaceuticals USA ("Teva") in 2009, and Sandoz Inc. ("Sandoz") in 2012. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr Laboratories ("Barr") from obtaining that company's thalidomide active pharmaceutical ingredient ("API").

86. Celgene's improper use of the REMS program as a shield to refuse to provide samples is contrary to FDAAA. FDAAA subsection f(8) states that "no holder of [a REMS-covered drug] shall use any element to assure safe use . . . to block or delay approval of . . . an [ANDA application]."[46]

ii. Celgene's REMS Programs are Post-Marketing Distribution Systems with No Legal or Practical Relation to Sales of Samples to Competitors

[45] Exhibit to MSJ Opp., Doc. No. 285-20.
[46] 21 U.S.C. § 355-1(f)(8).

87. Celgene's REMS distribution programs are post-marketing, commercial distribution programs. Celgene's REMS protocols do not discuss drug manufacturers conducting business with one another in the pre-marketing, drug development phase. Nor do Celgene's REMS protocols discuss or prevent distribution of samples to drug manufacturers.

88. Generic manufacturers' safety protocols are not required to be FDA-approved for that manufacturer to purchase samples of a REMS-subject drug. Robert West, former Deputy Director of OGD, commented that "a generic manufacturer is not required to submit its protocols to FDA before commencing bioequivalence studies."[47]

89. Clinical and pre-approval studies are not governed by REMS. In an August 2012 meeting with Celgene, FDA stated, "Celgene's REMS relates to a marketed situation and not a clinical trial where there is more control regarding administration of the product and the amount given is monitored and very limited."

90. A sample supply of a brand-name drug, including the API, is required to manufacture a generic equivalent. The API is used to conduct the required bio-studies and validation testing needed to be included in the generic manufacturer's ANDA.

91. Due to Celgene's REMS program, generic manufacturers are unable to purchase Thalomid and Revlimid samples in the United States through normal wholesale distribution channels. The restricted network that Celgene created forced incumbent competitors to purchase the drugs directly from Celgene, with FDA's endorsement.

iii. Celgene Refused to Sell Samples to Would-Be Competitors

1. Celgene Refused to Sell Samples to Mylan

[47] Exhibit to MSJ Opp., Doc. No. 285-15.

92. Celgene refused to sell Thalomid and Revlimid samples to Mylan, the second largest generic pharmaceutical manufacturer in the world.

93. Mylan began developing a generic thalidomide product on September 26, 2003. On October 27, 2003 Mylan requested OGD to provide guidance on prospective BE studies. OGD provided the requested guidance within the following year.

94. On December 22, Mylan requested thalidomide API from API suppliers GYMA Laboratories of America, Inc. ("GYMA") and Antibioticos to manufacture its formulation of thalidomide. By March 11, 2004, Mylan received thalidomide API from Antibioticos.

95. In September 2004, after Mylan was unable to gain access to Thalomid samples, FDA suggested Mylan contact Celgene to request samples. On October 5, 2004, Mylan's attorneys wrote Celgene a letter requesting to purchase 2,500 Thalomid capsules to conduct BE studies. Celgene failed to respond to the letter. Mylan repeated its request on May 3, 2005. By that time, Mylan had already completed safety training sessions for the handling and testing of thalidomide.

96. In a June 21, 2005 letter, Celgene explained that, pursuant to its S.T.E.P.S. program, Thalomid was not available through normal wholesale channels, and that it was against Celgene's policy to deal with third parties in the sale of Thalomid. This policy, to the extent it existed, was pretextual and not based upon any legitimate legal or regulatory concerns.

97. In unsealed internal emails from July 6, 2005, Celgene noted that "Mylan has had difficulty obtaining enough of Celgene's reference product to perform BE studies, so its ANDA submission is expected to be delayed until late in the third quarter of 2005."

98. On September 2, 2005, Mylan directly contacted Celgene and requested to purchase 3,360 Thalomid capsules to conduct BE testing. Mylan explained that the "FDA had

recommended that we contact you directly to request a sample" of Thalomid for BE testing, and that "obtaining samples through other traditional channels is nearly impossible."

99. On October 20, 2005, Celgene replied, claiming that it needed additional time to consider the request and "to avoid fetal exposure."

100. On November 15, 2005, Mylan used an intermediary to again request that Celgene sell it Thalomid samples for BE testing.

101. By December 2005, Mylan completed its scale-up of its experimental thalidomide batch. Mylan had, by that time, captured two-years' worth of stability data. The only remaining step to submitting its ANDA was to conduct BE studies against the RLD.

102. On December 19, 2005, Celgene stated that it would need FDA's approval to allow Mylan to purchase samples outside of the S.T.E.P.S. program: "[W]e recommend that you contact FDA's [Division of Special Pathogen and Transplant Products] to discuss the importance of the S.T.E.P.S. program to them." Celgene claimed that if FDA then "contacts us in writing and recommends that we violate our S.T.E.P.S. program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."

103. This was puzzling: in an internal report created in 2003 at Celgene's request, Celgene conceded that Mylan's patient monitoring system—already in place for another drug it was studying—was robust, comprehensive, and equivalent to the S.T.E.P.S. program.

104. Celgene's internal report concluded that Mylan's safety protocols "currently have very sophisticated patient monitoring systems for their respective clozapine products."[48]The report also stated that "it can be observed that the clozapine requirements are as comprehensive

[48] Exhibit to MSJ Opp., Doc No. 286-1.

as the S.T.E.P.S. program. Thus, Ivax and Mylan already have experienced [sic] with sophisticated monitoring systems."[49]

105. Next, Mylan requested FDA assistance to obtain the necessary Thalomid samples required for bioequivalence testing on January 11, 2006. In its letter, Mylan proposed protocols to ensure avoidance of fetal exposure.

106. On February 12, 2007, FDA replied, requesting an investigational new drug application ("IND") or study protocol so that it could "ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place," as a substitute for the S.T.E.P.S. program.

107. FDA's response continued:

> It is FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product. The agency believes that such bioequivalence studies can be conducted safely under either an IND or in circumstances that provide alternative assurance of patient safety. To ensure that the intention of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the S.T.E.P.S. program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution) testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.

108. On May 1, 2007, Mylan produced to FDA its proposed thalidomide safety protocols, which FDA reviewed, found "acceptable," and so notified Mylan on September 11, 2007.

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[49] *Id*.

109. On November 16, 2007, Mylan notified Celgene of FDA's approval, which directly addressed Celgene's pretextual justification for not providing samples. Celgene's senior executives and officers all admit that FDA is the ultimate authority on setting safety standards. Yet Celgene continued to deny Mylan's and others requests for drug samples for BE testing, using pretextual and obviously flawed safety concerns as its chief justification.[50]

110. Undeterred, Mylan continued to make requests over the next three years, including on December 4, 2007. Celgene continued to refuse to produce Thalomid samples, using delay tactics including requiring Mylan to produce burdensome, irrelevant, and duplicative information. Meanwhile, Celgene internally admitted that another prospective ANDA filer's request was "deficient in a way that the Mylan request is not."

111. On January 8, 2008, Celgene wrote Mylan requesting more information. Mylan responded on February 25, 2008 writing that it was prepared to provide all requested information and enclosed a confidentiality agreement. Celgene and Mylan negotiated the confidentiality agreement until June 24, 2008, when Celgene sent Mylan the executed agreement. Mylan sent Celgene another letter providing even more information and provided Celgene with proof of liability insurance covering any instances of injury relating to drug's misuse, and further provided an indemnity contract.

112. This contract, which was extensively negotiated, agreed to hold Celgene harmless in the event of any injury or misuse.

[50] On April 21, 2000, FDA sent Celgene a "Warning Letter" stating that "Celgene has engaged in promotional activities that state or suggest that Thalomid is safe and effective for use in treating multiple myeloma." With no generics on the horizon, Celgene was willing to play fast and loose with the safe distribution of Thalomid so long as it ensured increased utilization and increased profits.

113. Celgene wrote Mylan on August 1, 2008 that it was reviewing Mylan's documentation. Celgene's then-Regulatory Counsel testified that as of March 4, 2011, no "business people" at Celgene reviewed any of Mylan's documentation. Confoundingly, Celgene served an interrogatory response in an FTC investigation that two former CEOs, Sol Barer and Robert Hugin, "made the decisions on behalf of Celgene regarding Celgene's responses to pharmaceutical companies requesting to purchase Revlimid® and Thalomid® with legal advice from Celgene's Deputy General Counsel and then-Regulatory and Compliance Counsel." The referenced in-house counsel later testified in a separate litigation that they did not have any input into the requests, could not recall reviewing a single response to one of the information requests submitted to Celgene, or sitting in a meeting in which a response to a prospective ANDA filer's request was discussed. Upon information and belief, Celgene lied to the FTC in its interrogatory response.

114. Celgene wrote Mylan in a June 24, 2009 letter that there were "outstanding issues" with the information Mylan provided and requested nine additional categories of information. An internal Celgene email dated May 22, 2009 contained a project titled "Thalidomide Multiple Myeloma." The summary of the project stated "A generic thalidomide application was successfully delayed until at least June '09 in the USA. Celgene may further extend its exclusivity in the USA by using bioequivalence as a generic defense strategy…." Celgene's own emails show that it was never truly concerned with the safe distribution of its drugs, but rather used safety as a pretextual justification to prevent generic competition.

115. Celgene's refusal to sell Mylan samples, despite the existence of liability insurance and an indemnity contract, is further evidence Celgene was unwilling to negotiate in good faith with generic manufacturers to provide the requested drugs. This Court previously

held, based on these facts, that one could reasonably infer "that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid® or Revlimid® samples after FDA approval of Mylan's study protocols."[51]

116. Mylan estimates that had Celgene provided it with Thalomid samples in 2006, it would have filed a Paragraph IV Certification, Celgene would have initiated a patent infringement litigation and Mylan could have ultimately entered the thalidomide market in the third quarter of 2010.

117. By June 2007, Mylan began to develop its generic Revlimid. In internal emails from September 2007, Mylan planned to file its ANDA on December 27, 2009, was actively sourcing raw materials, had opinions on the blocking compound patents, and planned to design around the formulation patent.

118. In early 2009, Mylan endeavored to purchase lenalidomide supplies to manufacture a generic version of Revlimid. Celgene engaged in more delay tactics, causing Mylan to cease development efforts at various points while it attempted to procure Revlimid samples. Mylan manufactured its final lenalidomide formulation in June 2015.

119. In June 2010, in response to FTC interrogatories, Celgene explained to the FTC that "Celgene has decided not to sell REVLIMID® at the present time to manufacturers."[52]

120. Over two years later, through its counsel, Celgene wrote to the FTC that it was willing to "continue selling Thalomid and begin to sell Revlimid to drug companies, branded or generic, in quantities authorized by FDA sufficient to conduct bio equivalence studies for the purpose of preparing an Abbreviated New Drug Application [ANDA] with FDA."[53] Celgene, at

[51] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094, ECF No. 287, 27 (D.N.J. Oct. 3, 2018).
[52] Exhibit to MSJ Opp., Doc No. 286-4.
[53] *Id*.

no point prior to this email, ever sold Thalomid to generic drug companies to support BE studies for the purpose of preparing ANDAs. Celgene's letter continued: "[Celgene would] seek to set appropriate conditions with FDA for the sale of Revlimid similar to those it has set for the sale of Thalomid. . . ."

121. On August 14, 2012, Celgene wrote FDA claiming that the FDCA does not require an RLD sponsor to provide drug product to a proposed ANDA filer, and that FDA does not have authority to mandate any such requirement. Celgene even threatened that "any sale of Revlimid to a generic manufacturer will not be effectuated unless and until the FTC and the State of Connecticut Attorney General agree to close their investigation."[54]

122. On May 1, 2013, Mylan requested to purchase Revlimid samples from Celgene at market value. On May 14, 2013, Celgene wrote to Mylan that it would sell Revlimid to Mylan upon Celgene's review of Mylan's request and supporting documentation.

123. While not required to do so, Mylan sought FDA approval of its proposed safety protocols to avail itself of any assistance FDA might be able to offer in procuring Revlimid samples. FDA approved Mylan's protocols on July 29, 2013.

124. On March 11, 2014, Mylan wrote to Celgene explaining that it received all necessary FDA approvals. Celgene continued to refuse to provide samples, even, once again, after being informed of FDA approval for the proposed BE testing and safety protocols.

125. On March 20, 2014, Celgene again wrote to Mylan refusing to sell Mylan Revlimid samples. Exasperated with Celgene's tactics, Mylan brought a suit on April 3, 2014 against Celgene under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid.

[54] Exhibit to MSJ Opp., Doc No. 285-15.

126. Mylan alleged that Celgene cited safety concerns as a pretext for its continued refusal to provide samples of Thalomid and Revlimid, and that Celgene used a "playbook of obstruct[ion]" and "gam[ed] the regulatory system."[55]

127. On May 19, 2014, FDA notified Celgene that it accepted Mylan's submitted lenalidomide safety protocols and reiterated the FDCA's prohibition of using REMS to prevent ANDA filers from accessing drug samples.

128. The FTC filed an amicus brief in support of Mylan's suit against Celgene. The FTC noted that FDAAA was intended to prevent brand-name manufacturers from using REMS programs to impede generic competition, as Celgene was doing with Thalomid and Revlimid.

129. Further, in August 2012, the FTC sent counsel for Celgene an email detailing "a number of questions [raised] by the Bureau of Competition and the staff of the Connecticut Attorney's General office."[56]

130. These concerns included questions surrounding why Celgene had yet to provide samples of Thalomid to those requesting it, despite receiving explicit authorization from FDA to do so.

131. The letter also questioned what else Celgene would need to receive in order to authorize the sale of Revlimid to generic manufacturers: "in the interest of advancing our discussions and trying to reach a prompt resolution with you, we propose the FTC and Celgene meet together with FDA . . . to discuss what Celgene thinks it needs from FDA in order to be able to make prompt sales to generic firms."[57]

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[55] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094 (D.N.J. Apr. 3, 2014), Dkt. No. 1 ¶8.
[56] Exhibit to MSJ Opp., Doc No. 285-16.
[57] *Id.*

132. The FTC's Bureau of Competition ("BOC") followed up on this letter with another round of correspondence in February 2013.

133. In a letter to Celgene's counsel, Richard A. Feinstein, the director of the BOC stated "that there is a lot of concern here-at both the Bureau and Commission levels- about the time it has taken for your client to [redacted] of Revlimid capsules for bio-equivalence testing . . . the Commission's patience is wearing thin. We have reached a point where the staff may be instructed in the very near future to commence litigation."

134. Counsel for Celgene quickly forwarded this email to Celgene executives.

135. Most of Mylan's claims survived Celgene's motion to dismiss. Celgene subsequently filed its motion for summary judgment. On October 3, 2018, Celgene's motion was granted-in-part and denied-in-part.[58]

136. One of Mylan's expert witnesses in that litigation, Paul J. Jarosz, Ph.D., testified that Mylan's development process was typical for the pharmaceutical industry and that "[h]ad Mylan been able to purchase Thalomid so that it could dose its bioequivalence studies and receive an approval for its generic drug application, Celgene's '012 Patent and claim 2 of its '327 Patent would have not have prevented Mylan from launching its generic thalidomide product as the claims are invalid due to prior art and/or Mylan's formulation does not infringe them."[59]

137. Regarding generic Revlimid, Dr. Jarosz stated that "based on the simple nature of Revlimid and Mylan's previous experience developing thalidomide, it appears that Mylan could

[58] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094, ECF No. 287, 27 (D.N.J. Oct. 3, 2018).
[59] Exhibit to MSJ Opp., Doc No. 285-21.

have developed and filed an application for generic lenalidomide product by December 27, 2009."[60]

138. Dr. Jarosz's report confirms that the inability of generic drug manufacturers to bring versions of Thalomid and Revlimid to market was not due to internal issues or manufacturing defects. Instead, his report reinforces the fact that the only barrier to entry in the market was Celgene's conduct.

139. Mylan never received Revlimid samples, further elucidating that Celgene's refusal based on safety concerns was and continues to be a conveniently fabricated excuse to frustrate competition.

140. On August 1, 2019, Celgene announced that it reached a settlement with Mylan. On August 8, 2019, the District Court entered a consent judgment dismissing all claims with prejudice. Celgene disclosed that it agreed to pay $62 million to resolve all claims.

a. Mylan's Strong Safety Protocols Confirm and Illustrate the Pretextual and Unlawful Nature of its Refusal to Sell Samples to Would-Be Competitors

141. In September 2011, Sofgen Pharmaceuticals ("Sofgen") contacted Mylan regarding the potential purchase of Amnesteem for BE testing.

142. Like lenalidomide and thalidomide, Amnesteem is a known human teratogen, and was under FDA restriction for sale and delivery.

143. Sofgen knew of these restrictions and reached out to FDA prior to contacting Mylan to receive an assurance its iPLEDGE safety restrictions were acceptable and allowed it to receive a drug known to be a human teratogen.

[60] *Id.*

144. FDA sent Sofgen a letter in response, confirming Sofgen's iPLEDGE procedures were adequate under current FDA guidelines.

145. Mylan and Sofgen entered into successful negotiations surrounding Sofgen's purchase of Amnesteem samples from Mylan. This included the drafting of an indemnity agreement, discussions on the purchase price, and the method for payment and delivery. The sale was completed, and samples were delivered to Sofgen in Spring 2013.

146. Unlike Celgene, Sofgen and Mylan's discussions surrounding the purchase of Amnesteem show that receiving an FDA approval letter removes any perceived roadblocks to sharing a drug sample for BE testing.

147. Mylan's contract with Sofgen shows the process for obtaining generic drug samples can be completed in a short timeframe, and without the unnecessary and burdensome documentation Celgene requested from numerous generic manufacturers.

148. Further, another expert hired by Mylan in its lawsuit against Celgene, Jeff Fetterman, opined that Mylan's experience with the REMS process was robust and extensive, and it would have no issues implementing one for generic thalidomide and lenalidomide.[61]

149. As Mr. Fetterman stated in his report, "Mylan has extensive experience developing, implementing, and managing risk management programs, including several REMS programs with the same or similar restrictions and requirements as the S.T.E.P.S. and RevAssist programs."[62]

150. Mr. Fetterman continued and stated "[i]f Celgene had provided brand samples to Mylan and cooperated in developing a shared REMS program for thalidomide, the SS REMS

[61] Exhibit to MSJ Opp., Doc No. 286-2.
[62] *Id.*

development and FDA approval likely would have taken 18 to 24 months. Furthermore, this estimate may be conservative, as an alternative parallel agreement to sign onto the S.T.E.P.S. program would have taken even less time, possible in as few as 12 months. All of this work could have begun in advance of Mylan's ANDA approval. . . ."[63]

151. Mr. Fetterman's report details further how Celgene's refusal to provide drug samples due to noncompliance with REMS procedures was a misdirection and stall tactic that was not based in truth or fact.

2. Celgene Refused to Sell Samples to Exela

152. On May 31, 2006, Exela contacted Celgene and informed it of Exela's intention to file an ANDA for Thalomid. Exela stated it was having difficulty obtaining samples of this drug from other channels, much like the other generic manufacturers who had contacted Celgene. Exela requested a proposal for purchase within 10 days.

153. On June 27, 2006, Exela sent a follow up letter to Celgene again requesting to purchase Thalomid samples. In its letter, Exela noted the 10-day window for a purchase proposal had lapsed despite being received the day after it was sent.

154. On September 11, 2007, OGD wrote to Exela that its "proposed bioequivalence study protocol comparing Thalidomide Capsules, 200 mg to [Thalomid] is acceptable . . . ."

155. On December 11, 2007, OGD Director Gary J. Buehler sent a letter to Celgene's internal regulatory counsel, Kerry Rothschild stating that the "FDA has reviewed the bioequivalence protocol submitted . . . on behalf of Exela and has received sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects and has determined that Celgene may provide Exela with 500 units of Thalomid as

[63] *Id.*

indicated in FDA's letter to you dated February 8, 2007 for the purposes of conducting an *in vivo* bioequivalence study and *in vitro* dissolution testing."

156. Over a year later, on January 8, 2008, counsel for Celgene contacted counsel for Exela regarding the Thalomid purchase request.

157. In a response almost identical to ones given to other generic manufacturers, Celgene stated it did not believe it was obligated to turn over any samples. However, it continued that if Exela were to comply with a list of 10 demands for information, including, for example, proof of liability insurance and a history of product loss due to improper handling or tracking, Celgene would then "reconsider" its denial. Upon information and belief, Celgene never provided Exela with the requested samples of Thalomid.

3. Celgene Refused to Sell Samples to Lannett

158. On September 6, 2006, Lannett wrote a letter to FDA requesting BE recommendations regarding thalidomide capsules.

159. FDA's OGD responded to Lannett's letter on February 12, 2007. The OGD stated that "it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

160. The OGD commented that, to ensure Congress' intentions in enacting the Generic Drug Approval Provisions in Section 505(i) are carried out, the "FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid . . . for the purpose of conducting bioequivalence testing."

161. On February 8, 2007, FDA notified Celgene that "a study protocol would be reviewed by FDA to ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place" if a proposed generic manufacturer wished to conduct BE studies. FDA explained that it would "exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid for the purpose of conducting [BE] testing, when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the [BE] study will be conducted in such a manner as to ensure the safety of the subjects."

162. FDA's letter also requested Celgene submit a supplement to its own Thalomid NDA to the same effect. Celgene failed to submit this supplement, evidencing its own disregard for safety, non-monetarily incentivized circumstances.

163. Nevertheless, Celgene's then-regulatory counsel Kerry Rothschild testified that FDA's February 8, 2007 letter did not fully assuage Celgene's worry that a fetal exposure and birth of a baby with thalidomide-recognizable defects would have consequences to the value of Celgene's business.[64] Celgene Chief Executive Officer, Mark Alles, testified in 2016 that of the small number of fetal exposures to Thalomid between its development and 2016, the exposures "had minimal impact on the business as far as I know . . . ."[65]

164. In a July 26, 2007 letter to Celgene, Arthur P. Bedrosian, President and CEO of Lannett, wrote:

> In order to complete our bio-study, FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We

[64] Exhibit to MSJ Opp., Dkt. No. 285-1 at 36-27.
[65] Exhibit to MSJ Opp., Dkt. No. 286 at 185-186.

> will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase the product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

165. Upon information and belief, in September 2007, Lannett faxed to Celgene's Darnell Ragland, Manager, Customer Care of Celgene, a requested copy of the February 12, 2007 FDA letter, which authorized Lannett to acquire Thalomid supplies from Celgene.

166. Celgene continued to refuse Lannett's request. Celgene even went as far as actively screening any communication from Lannett directed towards Celgene regarding requests for samples of Thalomid.

167. In a September 28, 2007 internal email (only made publicly available in redacted form in 2018), a Celgene training alert ordered employees "**DO NOT PROCESS THE ORDER**" (emphasis in original) if a generic company calls or writes requesting to order Thalomid. Instead, the call center employees were directed to log the call, advise that a management team member would return the call, and to never transfer the call to someone higher up.

168. Employees were further instructed to forward any similar correspondence via fax to one of their supervisors.

169. Then, on October 18, 2007, Lannett wrote a letter to Mr. Ragland reiterating Lannett's request so that it could conduct BE testing needed to obtain approval to market its generic thalidomide.

170. On January 8, 2008, Celgene advised Lannett that it would not provide samples of Thalomid to Lannett. Rather, Celgene requested Lannett produce voluminous and unnecessary documentation in order for Celgene to "reconsider" the request.

171. On January 14, 2008, Lannett filed a complaint against Celgene seeking, among other things, mandatory injunctive relief requiring Celgene to provide samples of Thalomid as contemplated by the February 12, 2007 FDA letter.[66] The case was dismissed without prejudice.

172. Lannett then provided almost all of the information that Celgene requested except its highly confidential FDA Form 483 inspection reports, which relate to the routine inspection of manufacturing facilities, given that the Thalomid samples Lannett requested would not be used for manufacturing, but rather for BE studies that it would perform overseas.

173. Lannett submitted its proposed study for FDA review, and received approval on August 11, 2008.

174. Lannett refiled its Complaint on August 15, 2008 alleging violations of the Sherman Act and seeking injunctive relief. Celgene filed its motion to dismiss on November 4, 2008. The motion was summarily denied on May 13, 2010.[67]

175. Celgene reached a confidential settlement with Lannett in 2011.

176. In its 2012 Annual Report, Lannett stated that "a sizable portion of our fiscal 2013 R&D budget is earmarked for two large market opportunity projects, C-Topical and Thalidomide." Its 2013 Annual Report stated that Lannett "successfully passed critical milestones for submitting a product application for Thalidomide." As discussed below, Lannett eventually filed a thalidomide ANDA in late 2014.

177. Upon information and belief, the settlement between Celgene and Lannett may have contained anticompetitive terms, such as a promise to delay submission of the ANDA.

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[66] *Lannett Company, Inc. v. Celgene Corp.*, No. 08-cv-0233. (E.D. Pa.).
[67] Order, *Lannett Co., Inc. v. Celgene Corp.*, No. 08-cv-3920, ECF No. 27 (E.D. Pa. May 13, 2010); *see also* Order, No. 08-cv-3920, ECF No. 42 (E.D. Pa. March 31, 2011) (denying renewed motion to dismiss).

178. The anticompetitive effect of Celgene's conduct was to delay Lannett's ANDA. Though Lannett began requesting Thalomid samples in 2006, it was unable to obtain such samples due to Celgene's delay until after December 2011 and did not file its ANDA until 2014, at which time Celgene filed a sham patent litigation, discussed below, all to delay Lannett's thalidomide product. As of today, there is no generic thalidomide on the market.

4. Celgene Refused to Sell Samples to Dr. Reddy's

179. Dr. Reddy's is a prescription drug manufacturer based in Telangana, India. It has been developing generic prescription drugs in the United States since 1994.

180. Dr. Reddy's requested samples of Revlimid from Celgene to perform BE testing in August 2008. Celgene did not reply to this request.

181. Dr. Reddy's repeated its request in December 2008. Celgene offered a single sentence reply in January 2009: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."

182. In its request to Celgene, Dr. Reddy's assured Celgene any testing it performed would comply with FDA guidelines, using methods similar to Celgene's REMS program known as RevAssist to insure proper handling of the subject drugs.[68]

183. Dr. Reddy's filed a citizen petition with FDA in June 2009, alleging that Celgene was refusing to provide samples to a generic drug manufacturer to perform BE testing.

184. Celgene once again premised its refusal on its REMS program, despite FDA's previous guidance.

185. In 2016, Dr. Reddy's filed an ANDA for a generic lenalidomide product. As discussed below, Celgene then sued Dr. Reddy's claiming patent infringement.

[68] Exhibit to MSJ Opp., Doc No. 285-6.

5. Celgene Refused to Sell Samples to Teva

186. Teva requested a total of 5,000 Revlimid Capsules in 5, 10, 15, and 25 mg dosages from Celgene to perform BE testing in March 2009.

187. In its letter to Celgene, Teva stated that its ". . . procedures for conducting any required testing involving lenalidomide and the Revlimid drug product provided by Celgene Corporation will fully comply with FDA requirements. Teva's controls with respect to lenalidomide with be comparable to the RevAssist program."

188. In April of 2009, Celgene responded to Teva's request, and in a one sentence reply, stated "[t]his letter is to inform you that your request for 5,000 capsules of REVLIMID (lenalidomide) in varying strengths is declined."

189. Celgene's refusal to provide Teva with samples of Revlimid follows a similar course of conduct as other generic pharmaceutical companies.

6. Celgene Refused to Sell Samples to Watson

190. In June of 2009, much like the other generic manufacturers described above, Watson contacted Celgene to acquire samples of Thalomid and Revlimid for BE testing.

191. In its request, Watson assured Celgene the process by which it would handle the samples of these drugs would fully comply with a restricted distribution system similar to RevAssist.

192. Furthermore, Watson assured Celgene that FDA guidelines would be followed and no drug would be distributed in violation of these guidelines, which would have been unlikely to happen given Watson's vast experience and expertise in the generic drug manufacturing market.

193. In July 2009, despite Watson's assurances that the requested samples would be handled in a safe, effective, and FDA-compliant manner, Celgene responded with a list of 10

pieces of evidence and documentation Watson would need to provide before Celgene would consider Watson's request. Celgene indicated it would respond to Watson's request for Revlimid in a separate letter.

194. Tellingly, Celgene did not say satisfying these 10 requirements would facilitate a prompt sale of the samples, merely that at that time Celgene would "consider" it.

195. Upon information and belief, like the generic manufacturers before and after, Watson was unable to obtain the samples of Thalomid and Revlimid it requested, with no logical reason provided.

7. Celgene Refused to Sell Samples to Sandoz

196. In May of 2012, much like the other generic manufacturers described above, Sandoz contacted Celgene attempting to acquire samples of Thalomid and Revlimid for BE testing.

197. In response, Celgene refused to provide the samples, and instead listed nine prerequisites Sandoz had to satisfy before it would consider selling the requested samples.

198. These prerequisites included that Sandoz provide "Proof of liability insurance sufficient to cover events associated with thalidomide and lenalidomide," "[p]olicies for biohazard handling, disaster recovery plans as well as the storage and use of teratogenic products," and "[w]ritten confirmation that an IND is in effect or a study protocol . . . has been approved by FDA."

199. Like its correspondence with other generic manufacturers wishing to obtain drug samples, Celgene referenced the REMS procedures as a reason it could not immediately supply Sandoz with samples, despite FDA approval of Sandoz's procedures.

200. Upon information and belief, like the generic manufacturers before it, Sandoz was unable to obtain the samples of Thalomid and Revlimid it requested.

201. Celgene has provided Thalomid and/or Revlimid to no generic manufacturer.

iv. Celgene Had No Legitimate Business Justification for Refusing Samples to Would-Be Competitors Because Its Safety Concerns Were Pretextual

202. While Celgene refused to supply any potential ANDA sponsor the necessary and required samples of Thalomid and/or Revlimid based on safety concerns, it authorized its competitive intelligence firm to purchase, handle, and transfer thalidomide with no safety training required.

203. In 2003, Celgene authorized GBMC to purchase thalidomide API from a European supplier, Alan Pharmaceuticals. In fact, GBMC was authorized by Celgene to use undercover purchases to obtain samples of thalidomide API from various API suppliers. In an undated letter, GBMC detailed the sequence of events it used to acquire, at Celgene's request, thalidomide samples outside the normal chains of distribution. This sequence included falsifying prescriber names and permitting GBMC (a non-pharmaceutical company with no experience in handling teratogenic drug product) to handle thalidomide samples, all without a formal tracking mechanism. Celgene's Senior Director of Market Research testified in a previous litigation that he did not notify Celgene's legal department of these undercover purchases, that Celgene did not do background checks on individuals that would be handling the drug product, and that he could not recall whether the purchased product was in its proper packaging when Celgene received it, or who at Celgene received it.

204. These Celgene authorized transactions did not comport with any safety protocol.

205. Celgene willingly and frequently provided access to Thalomid and Revlimid to non-competitor research organizations, outside the REMS process and without FDA guidance or approval for the safe handling of the drug products, for the purpose of conducting clinical studies.

206. Celgene provided Revlimid for at least 3,600 different research and investigational studies that all operated outside the REMS process. Celgene similarly provided Thalomid for over 100 investigator-initiated trials ("IIT").[69]

207. For example, Celgene provided Thalomid and Revlimid to the Johns Hopkins School of Medicine for clinical trials and provided Revlimid to Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, TX.

208. An IIT process is initiated when an investigator submits a Letter of Intent ("LOI") outlining a proposal. The brand company, here Celgene, then reviews the proposal. Celgene testified that it tried not to review the full protocol, but rather would typically review a simplified synopsis, along with the nature of the request, the budget, and the amount of drug requested. The request, typically adjudicated within two months, does not require in-house counsel assistance. Celgene has never denied an IIT proposal due to fetal exposure safety concerns.

209. After approving an IIT proposal, Celgene works with the investigator to draft a study protocol and consent form which then is submitted to FDA for approval. Celgene had admitted that FDA's approval gives Celgene confidence in the safety of the trial. Celgene then supplies Thalomid or Revlimid to the investigator to initiate the study.

b. Celgene Induced Pharmacies and Ingredient Suppliers into Anticompetitive Exclusive Contracts to Prevent Generic Manufacturers from Accessing APIs

210. As part of its multi-faceted and decades long scheme to unlawfully monopolize the markets for Thalomid and Revlimid, Celgene not only refused to sell samples to competitors,

[69] IITs are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups, cohorts or physicians.

it also executed exclusive contracts with pharmacies and ingredient suppliers designed to delay competitors from obtaining the needed resources to file an ANDA. As Celgene could not exhaust API supply from these suppliers, the exclusivity provisions had no business justification and were executed entirely to deny competitors access to API, thereby foreclosing generic entry into the Thalomid and Revlimid markets. On information and belief, Celgene prevented Barr Laboratories, Inc. from obtaining API supply from Seratec, and Plaintiff believes that after a reasonable opportunity for discovery it will uncover more anticompetitive exclusive contracts.

211. After FDA approved Celgene's Thalomid, Barr Laboratories, Inc. ("Barr") a generic drug manufacturer, sought to develop a generic version of thalidomide. In order to secure approval of an ANDA, a proposed generic manufacturer must designate the API manufacturer in the ANDA. The ANDA applicant must submit a Drug Master File ("DMF") from the API supplier to FDA, which is evaluated with the ANDA.

212. In approximately 2004, Barr succeeded in procuring thalidomide API from Seratec S.A.R.L. ("Seratec"), a French supplier, to develop a generic version of Thalomid by September 2005. Barr submitted its ANDA to FDA and was waiting to receive a DMF letter from Seratec.

213. Barr's ANDA proposed a skinny label, only seeking approval for ENL, and not MM.

214. While Barr and Seratec were finalizing negotiations, Celgene and Seratec entered into an exclusive supply agreement for thalidomide. Upon information and belief, Celgene demanded exclusivity from Seratec to interfere with Barr's ability to market generic Thalomid.

215. Inducing this exclusivity agreement was a nakedly anticompetitive action undertaken by Celgene to ultimately delay and exclude Barr from entering the market for

Thalomid. First, Celgene had a separate API supplier that independently was filling its own API supply needs and had sufficient supply to meet projected growth requirements. Second, Seratec itself had sufficient resources to meet all of Celgene's needs without exhausting supply, leaving Seratec capable of supplying Barr but for the exclusivity provision.

216. Due to Celgene's anticompetitive scheme, Seratec, therefore, could no longer supply Barr with its thalidomide API. FDA did not accept Barr's ANDA due to deficiencies in providing a DMF from Seratec.[70]

217. Consequently, Barr was forced to find a different thalidomide supplier and repeat testing, causing it great expense and delay in launching generic thalidomide.

218. On February 27, 2006, Celgene's competitive intelligence firm, GBMC, updated Celgene that Barr completed BE testing and was planning on filing a thalidomide ANDA in the second quarter of 2006 using API from either Antibioticos of Italy or Shilpa of India. GBMC noted that "[t]hese companies were being used to replace the Seratec API that Barr originally was using for its ANDA."

219. After securing a new supplier and performing new BE studies and validation testing, Barr submitted its thalidomide ANDA on September 22, 2006. The ANDA showed that Barr's generic product was bioequivalent to Celgene's Thalomid. FDA accepted Barr's thalidomide ANDA for filing on December 4, 2006.

[70] It was unclear to Celgene how Barr acquired Thalomid samples for BE testing in 2005. In Celgene's response to interrogatories in a separate litigation recently made public, Celgene noted "Celgene informed FDA of its belief that Barr had acquired Thalomid® capsules from a pharmacy in Astoria, New York in violation of the requirements of the S.T.E.P.S. program. FDA informed Celgene that it did not intend to 'recapture' these capsules from Barr, and that the manner in which Barr obtained Thalomid® for use in its bioequivalency testing would not affect FDA's consideration of any subsequent ANDA with respect to thalidomide that Barr might file."

220. Celgene subsequently initiated a patent infringement lawsuit against Barr for its thalidomide ANDA, as discussed more thoroughly below, initiating an automatic 30-month stay of FDA's approval of Barr's ANDA.

221. GBMC predicted that Barr could be expected to receive FDA approval of its thalidomide ANDA in the first quarter of 2009.

222. In a May 2009 email between executives at Celgene, which contained the minutes of a previously held internal meeting, these executives discussed Barr's attempt to market generic thalidomide in the USA.[71]

223. According to the minutes of the meeting: "Dianne Azzarello Regulatory Canada discussed possible ways to defend Thalidomide against generic infiltration in the USA. From her experience in working with generic drug providers she is of the opinion that [Celgene was] able to use bioequivalence as generic defense strategy. The team supports this notion. If generic companies have to effectively prove that they are at least equivalent to what Celgene has to offer including Celgene's RiskMap before making product available on the market."

224. The meeting participants also discussed paying for research and publishing research papers stating generic manufacturers' version of Thalomid were not bioequivalent: "Diane Azzarello and Henry Lau are working with Dr. Iain McGilveray who will publish a paper providing evidence that many other formulations of thalidomide available are not bio equivalent to Celgene's Thalomid. We may also include our simple formulation and its chemical properties as rationale. Funding for this publication is estimated to be $40k $60k."

225. These internal discussions are further evidence Celgene was not negotiating the sale of sample drugs to generic manufacturers nor executing contracts with exclusivity

[71] Exhibit to MSJ Opp., Doc. No. 284-4.

provisions with suppliers in good faith, instead seeking to foreclose generic entry into the markets for Thalomid and Revlimid.

c. Celgene Fraudulently Obtained Patents for Thalomid and Revlimid and Their Associated Safety Distribution Protocols

226. Even when a generic manufacturer managed to obtain a sample of Thalomid or Revlimid, Celgene was still able to unlawfully block them from the market by obtaining numerous redundant patents related to the composition, and plans for safe distribution, of Thalomid and Revlimid. Celgene's construction of a patent fortress was part of its multi-faceted and decades long scheme to monopolize the markets for Thalomid and Revlimid.

227. These types of patents generally claim the use of registries to register patients, prescribers, and pharmacies, testing and regular re-testing of the patient for signs of harmful side effects associated with the drug (including pregnancy testing), counseling patients about the risks associated with the drug, limiting the dispensed amount of the drug, and prescribing and dispensing the drug after analyzing the risk and determining that it is acceptable.

228. The patent on Celgene's active ingredient in Revlimid, the '517 Patent, expired in 2019. The last of Revlimid's patents listed in the Orange Book, the '800 Polymorph Patent, expires in 2028.

229. Celgene, armed with its fraudulent patents, serially filed sham patent infringement lawsuits and citizen petitions against any Paragraph IV ANDA filer. Through these serial sham litigations, Celgene was able to successfully—and illegally—block generic entrants from the Thalomid and Revlimid markets. *See infra*, Part VII.e.

i. Celgene Failed to Disclose Material Information on Patentability of the Drug Composition Patents

230. The original, core patent for the composition of Celgene's thalidomide-derived drugs is the '517 Patent, filed in 1996. Thalidomide, the drug on which Revlimid is based, was

first marketed in 1957. The innovations on which the '517 Patent is based are obvious in light of the innovations and research conducted long before Celgene began its effort to bring Thalomid and Revlimid to market; thus, the '517 Patent and the subsequent patents derived from it are invalid.

231. Thalidomide was found to be immunotherapeutic in the 1960's, meaning it was known that thalidomide could treat diseases by inducing, enhancing, or suppressing an immune response. Extensive scientific literature establishes the immunomodulatory properties of thalidomide and its derivative, lenalidomide, the active ingredient in Revlimid. It was well established that thalidomide has immunomodulatory properties, that thalidomide derivatives have the same immunomodulatory properties as thalidomide, that thalidomide was effective in the treatment of autoimmune diseases, that thalidomide derivatives inhibited Tumor Necrosis Factor Alpha, and that thalidomide is an angiogenesis inhibitor which also aids in the treatment of multiple myeloma. There has been nothing unexpected or unanticipated about the effects or uses of Thalomid or Revlimid over the precedent scientific literature. In filing the '517 Patent with the USPTO, Celgene cited none of these precedents. Celgene failed in its duty to disclose, and the USPTO examiners were not aware of, this key prior art when the '517 Patent was granted. Under 37 CPR 1.56, this undisclosed but publicly available prior art and research from decades earlier anticipate and invalidate the patent.

232. In 2003, Celgene filed the '012 Patent for thalidomide, a drug that had first been used almost half a century prior. Again, Celgene cited none of the relevant precedent above in its USPTO filing. Under 37 CFR § 1.56, Celgene had a duty to disclose information material to patentability. For the drug composition patents, as well as the distribution patents discussed

below, Celgene has shown a pattern of omitting important precedents in USPTO filings for Thalomid and Revlimid.

1. Celgene Tried to Extend its Monopoly by Filing Redundant Drug Composition Patents Based on Previously Ill-Gotten Patents

233. To extend its monopoly on the sale of thalidomide derivatives, Celgene began filing additional patents on the polymorphic forms of lenalidomide. Polymorphs, also known as solvates or crystalline forms, of previously patented compounds are routinely developed as a standard practice in the pharmaceutical industry, according to a US patent examiner in a rejection of one of Celgene's polymorph patent applications, and generally not separately patentable.

234. Nonetheless, Celgene managed to get the USPTO to approve its polymorph patents and list them in the Orange Book. These patents—the '800 Patent and the '217 Patent—expire in 2027 and 2024, respectively. Since these patents have the latest expiration dates of any patents associated with Thalomid or Revlimid, they have been key patents cited in repeated attempts by Celgene to block generic competitors from the market. Celgene routinely cites these polymorph patents against generic manufacturers that have filed generic Thalomid and/or Revlimid ANDAs.

235. In doing so, Celgene has also repeatedly exposed the polymorph patents to charges of invalidity and has repeatedly settled instead of testing the strength of these patents in court for fear of the result. When Natco Pharma Limited ("Natco Pharma") filed an ANDA for its generic version of lenalidomide, Celgene brought suit against it, Watson, and Arrow

International Ltd., ("Arrow") (collectively, "Natco") claiming infringement.[72] The parties agreed to a Markman hearing to settle the meaning of disputed patent terms. Citing Celgene's own clarified definition of the term "hemihydrate," Natco amended its invalidity contentions to the '800 Patent, arguing that it was invalid for indefiniteness, lack of enablement, and lack of written description. When Celgene was unable to prevent Natco from raising these amended invalidity contentions, Celgene quickly settled with Natco, allowing Natco to share certain of its market share prior to the expiration of its patents. This settlement agreement likely contained a "no authorized generic" provision dividing the market between Natco and Celgene. Having learned a dangerous lesson, Celgene did what was necessary to avoid a similar Markman hearing over the meaning of "crystalline" in its subsequent litigation against Dr. Reddy's.[73]

236. Celgene knows that the overbroad terms of its redundant polymorph patents are an attempt to block generic competitors from bringing non-infringing products to market where the generic manufacturer has developed a suitable workaround to Celgene's patents. The claims of Celgene's other polymorph patent, the '217 Patent, also call out crystalline and hemihydrate forms, and are invalid for the same reasons as the '800 Patent. These patents, like the '517 patent from which they were derived, were obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent. Celgene's failure provides an independent basis for invalidity. These polymorphs are also obvious variants of the composition of matter patent, adding a further basis for invalidity. Finally, based on

[72] *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982 (D.N.J. Jul. 9, 2015). Celgene alleged that while Natco Pharma filed the ANDA, Arrow assisted Natco Pharma in preparing and filing the ANDA, and Watson prosecuted the ANDA before FDA.

[73] Letter to Court, *Celgene Corp. v. Dr. Reddy's Laboratories Ltd.*, 2:16-cv-7704 (D.N.J. Mar. 23, 2018), ECF No. 77. On the date that its responsive Markman pleadings were due, Celgene filed a letter informing the court that it resolved its claim construction disputes with Dr. Reddy's and would not be filing responsive pleadings.

Celgene's own representations in the Markman hearing that was held in the *Natco* litigation, the claims of the patent are unenforceable as overbroad.

237. The anticompetitive effect of Celgene's conduct with respect to the composition patents was to erect a fortress of protection for Celgene's continued monopoly.

ii. Celgene Failed to Disclose Material Information on Patentability of the Distribution Method Patents

238. As discussed above, in 1998, Celgene only listed the '501 Patent in the Orange Book in connection with Thalomid. Since then, it has listed numerous additional patents, including the '720, '976, '977, and '784 patents (together with the '501 Patent, the "Distribution Method Patents") in the Orange Book as covering Thalomid.

239. The '501 and '720 patents were invalidated by the Patent Trial and Appeal Board ("PTAB") on October 26, 2016.[74]

240. The PTAB found the '501 Patent invalid as obvious over the combined disclosures of three asserted prior art references as representative of the level of ordinary skill in the art.

241. Guidance regarding the clinical use and dispensing of thalidomide was provided by an existing publication in 1994 that identified a patient subpopulation of women who could and wished to become pregnant, warning that they should not be treated with Thalomid, and recommending counseling on the risks of thalidomide as well as the use of contraception.[75]

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[74] See *Coalition for Affordable Drugs VI LLC, et al., v. Celgene Corp.,* IPR2015-01092, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01092; IPR2015-01096, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01096; IPR2015-01102, Paper No. 75 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01102; IPR2015-01103, Paper No. 76 (Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01103 ("*Coalition*").

[75] R.J. Powell and J.M.M Gardner–Medwin, *Guideline for the clinical use and dispensing of thalidomide*, POSTGRAD MED. J. 79, 901–904 (1994) ("Powell").

242. Further guidance was also provided by the existing pregnancy-prevention program for women users of Accutane, a Vitamin A analogue of isotretinoin and a known teratogenic drug. Accutane was subject to a program of preventative measures, such as pregnancy-risk warnings on packaging, targeting of women of childbearing age for the pregnancy-prevention program, and communication between physicians and patients regarding the drug's teratogenic risk and the need to prevent pregnancy.[76]

243. Guidance for the use of a national database to register prescribers, pharmacies, and patients as a way to restrict access to drugs that could be potentially hazardous was also published well before the '501 Patent was filed, such as the nation-wide registry for patients requiring clozapine, a potent anti-psychotic drug with potential for serious side effects.[77]

244. The PTAB found that a person of ordinary skill in the art would have understood how to implement Powell's teachings in clinical and pharmacy settings in view of the Accutane Pregnancy Prevention Program and the Clozaril (clozapine) controlled distribution model outlined in Dishman. The PTAB was not persuaded by Celgene's argument that the prior art did not specifically single out men who could impregnate a woman as a subgroup, noting that a skilled artisan would have recognized that the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects if the male was to impregnate a female.[78]

245. The PTAB found the '720 Patent invalid as obvious over the combined disclosures cited against the '501 Patent for the original S.T.E.P.S. program, while finding that

[76] Allen A. Mitchell et al., *A Pregnancy–Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, NEW ENG. J. MED. 333:2, 101–06 (Jul. 13, 1995) ("Mitchell").
[77] Benjamin R. Dishman et al., *Pharmacists' role in clozapine therapy at a Veterans Affairs medical center*, AM. J. HOSP. PHARM. 51, 899–901 (Apr. 1, 1994) ("Dishman").
[78] *Coalition,* IPR2015–01092, Paper No. 73.

the inherent dangers of Thalidomide would drive someone of ordinary skill in the art to proactively improve the system. Citing U.S. Patent No. 5,832,449 (issued Nov. 3, 1998, "Cunningham"), which describes an approval code used by prescribers and pharmacies to track and manage pharmaceutical products, the PTAB found that a person of ordinary skill in the art could predict that such an approval code could be utilized by prescribers and pharmacies to track and manage Thalomid and Revlimid. In light of this prior art, the PTAB invalidated the '720 Patent as obvious.

246. As the PTAB noted, "[w]hen it benefitted [Celgene's] interests before FDA, [Celgene] freely admitted that its 'plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane … and Clozaril."[79] Before the USPTO however, Celgene repeatedly failed to disclose the very materials that it relied on in presenting its program to FDA, along with other similar prior art such as the Clozaril Patient Monitoring Service and numerous published works describing the features of REMS programs similar to Celgene's original and modified S.T.E.P.S. programs.

247. On July 30, 2019, the Federal Circuit affirmed the findings of the PTAB invalidating the '501 and '720 patents for obviousness.[80]

248. The '976 Patent, the '977 Patent, and the '784 Patent, filed more than three years later, are nearly identical to the invalidated '501 and '720 patents. In fact, many of these patents were so similar that Celgene did not even bother changing the title or abstract describing the patent.

[79] IPR2015-01092, at 24 (P.T.A.B. Oct. 26, 2016).
[80] *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019).

249. Celgene also listed the ’886 Patent in the Orange Book in connection with Thalomid on November 20, 2012.

250. Celgene listed each of these patents in the Orange Book for both Thalomid, and later Revlimid, with full knowledge that protocols for the safe distribution of dangerous drugs like Thalomid and Revlimid have been in public use for years before Celgene filed any of its patent applications.

251. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud and are unenforceable. Celgene caused these patents to be listed in the Orange Book with knowledge that they were fraudulently obtained and are unenforceable. Celgene’s withholding of material information on patentability with the intent to deceive the USPTO was done for the anticompetitive purpose of excluding generic competitors and maintaining a market monopoly.

252. The public prior use and/ or publication of Celgene’s claimed “Distribution Method” inventions include:

1. The Clorazil Patient Monitoring Service (“the CPMS”)

253. The CPMS is a program for the distribution of Clorazil™. Clorazil treats schizophrenia. A major side effect of Clorazil is agranulocytosis, a potentially fatal blood disorder.

254. Clorazil is distributed through the CPMS, which uses a national registry for patients, prescribers, and pharmacies. This registry identifies and reduces the risk of Clorazil-related complications.

255. The CPMS uses a computerized registry that includes patient information such as white blood cell counts to determine risk factors. The CPMS also tests white blood cell counts prior to starting Clorazil therapy. The CPMS mandates prescribing and dispensing only a limited

supply of Clorazil after the prescriber determines that the risk is acceptable and provides the dispensing pharmacy with a report containing white blood cell counts and the doctor's opinion that the patient is eligible to receive required Clorazil. Additionally, the CPMS contains protocols for discontinuing treatment if the doctor determines, based on weekly blood tests, that the risk becomes unacceptable. Weekly refills are only provided after the same criteria for the initial dispensation are met again at the start of each week.

256. The CPMS qualifies as prior art to the claims of the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one year before the earliest priority date of the Distribution Method Patents and the '886 Patent.

257. The applicants of those patents, their agents, and/or their attorneys did not disclose the CPMS to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

2. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, 47(1):52-56 (1996) ("Honigfeld I")

258. Honigfeld I describes details of the CPMS and qualifies as prior art to the Distribution Method Patents and the '886 Patent because it was publicly available and accessible more than one year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent.

259. The applicants, their agents, and/or their attorneys did not disclose Honigfeld I to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

3. Honigfeld, *et al*., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience with the Clozaril

National Registry," J. *Clin. Psychiatry* 59 (suppl 3): 3-7 (1998) ("Honigfeld II")

260. Honigfeld II also details the protocols of the CPMS and qualifies as prior art to the '501 and '976 patents because it was publicly available information prior to the earliest priority date of the '501 and '976 patents. Honigfeld II qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. § 102(b), because it was publicly available information more than one year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

261. The applicants, their agents, and/or their attorneys did not disclose Honigfeld II to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

4. The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("the Guide")

262. Details of the CPMS are described in the Guide, which qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available prior to the earliest priority date of the '501 and '976 patents. The Guide qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. §102(b), because it was publicly available more than one year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

263. The applicants, their agents, and/or their attorneys did not disclose the Guide to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

5. The ACCUTANE® Pregnancy Prevention Program ("the PPP")

264. The PPP is a program for the distribution of Accutane, known generically as isotretinoin. The PPP was developed and implemented to prevent fetal exposure to isotretinoin. The PPP included an information package for physicians warning of the risks of dispensing the

drug to pregnant women, a patient informed consent form containing warnings detailing the risks associated with Accutane and the requirements to receive Accutane and required pregnancy testing and birth control counseling before the patient started a course of Accutane therapy. It also required a patient survey on compliance.

265. The PPP qualifies as prior art to the claims of the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent.

266. The applicants, their agents, and/or their attorneys did not disclose the PPP to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

6. The Accutane PPP Package, a 1994 patent and prescriber information package for Accutane, distributed by Roche Pharmaceuticals ("the PPP Package")

267. The PPP Package described details of the PPP. It qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was publicly available more than one year prior to the earliest priority date of the Distribution Method Parents and the '886 Patent.

268. The applicants, their agents, and/or their attorneys did not disclose the PPP Package to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

7. A Centers for Disease Control public meeting entitled "Preventing Birth Defects Due to Thalidomide Exposure" and transcript from March 26, 1997 ("the CDC Meeting" and "the CDC Transcript")

269. On March 26, 1997, the CDC held a public meeting to discuss thalidomide and its associated risks. The meeting was attended by at least two Celgene employees: Dr. Jerome Zeldis, the then-Vice President of Medical Affairs at Celgene, and Mr. Bruce A. Williams, a named inventor for the Distribution Method Patents and the '886 Patent.

270. The transcript of the CDC Meeting shows that the PPP and the CPMS were discussed, as was the use of the protocols in those two systems in designing a similar protocol for thalidomide.

271. The CDC Meeting attendees discussed potential elements to be part of a thalidomide distribution program, including: (1) patient, pharmacy, and prescriber registration; (2) counseling patients about the risks of thalidomide and the need for contraception; (3) required pregnancy testing before thalidomide is prescribed; (4) monthly testing thereafter; (5) providing proof that the patient is not pregnant before the drug can be dispensed and providing contraceptives with the drug; (6) limiting the length of the prescription to a monthly supply; and (7) requiring return to the prescriber before refilling the prescription.

272. The CDC Transcript was publicly available under the Freedom of Information Act more than one year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent. It therefore qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C § 102(b).

273. The applicants, their agents, and/or their attorneys did not disclose the CDC Meeting or the CDC Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

8. Zeldis, *et al*., "S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("Zeldis")

274. Zeldis qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available more than one year prior to the earliest priority date of the '720, '977, and '784 Patents.

275. Zeldis is co-authored by Celgene employees, including Zeldis and named inventor Williams. It described the S.T.E.P.S. program Celgene developed with the guidance of FDA, to monitor and control access to thalidomide. Zeldis states that the S.T.E.P.S. protocol is "based in part on experience gained with other drugs—specifically isotretinoin and clozapine— that offer important clinical benefits but carry the potential for serious harm."

276. Zeldis states:

> Celgene has incorporated elements of both these successful programs into the S.T.E.P.S.™ program for controlling the distribution of thalidomide. Educational materials for patients and physicians and label warnings similar to those used in the isotretinoin program are coupled with clinician and patient registration and testing similar to those used in the clozapine program.

277. Zeldis cites Honigfeld I and Honigfeld II in its discussion of Clorazil.

278. The applicants, their agents, and/or their attorneys did not disclose Zeldis to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

9. The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting ("the CDER Meeting" and "the CDER Transcript")

279. The September 4-5, 1997 CDER Meeting was recorded in a publicly-available transcript and at least seven Celgene employees, including named inventor Bruce Williams who made a presentation on preventing fetal exposure to thalidomide, attended the meeting.

280. Williams stated:

> [w]e recognize that there may be some models in the marketplace today

> which could serve as at least a starting point in our thinking as we develop this program. Two of them came to mind that I would like to just speak very briefly to, to indicate why we feel that they are relevant models, but also where we feel they may not go far enough for this particular circumstance. The first is one that this committee, particularly, is very familiar with. And that is Roche's Accutane, used to treat severe acne, and known to be a human teratogen.

281. Williams described the Accutane system, the PPP, and its purported drawbacks, which he described as a lack of a mandatory registry and an inability for a pharmacist to determine at dispensing whether the patient has participated in Roche's program.

282. He noted that the PPP's purported drawbacks drove Celgene to analyze the CPMS protocol, to which he stated:

> In looking at how Sandoz structured this [Clozaril] system, we began to see that by taking elements from the Roche program [Accutane], elements from the Clozaril program and other unique elements, we would create a system that really would be state of the art, represent a significant step, we believe, forward in the ability to make drugs like thalidomide available to patients who need it, while at the same time providing a very high margin for protection.

283. The CDER Transcript qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act prior to the earliest priority date of the Distribution Method Patents and the '886 Patent. The CDER Transcript also qualifies as prior art to the '720, '977, and '784 Patents under 35 U.S.C. § 102(b), because it was publicly available information under the Freedom of Information Act more than one year prior to the earliest priority date of the '720, '977, and '784 Patents.

284. The applicants, their agents, and/or their attorneys did not disclose the CDER Meeting or the CDER Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

10. The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" ("the NIH Meeting" and "the NIH Transcript")

285. The NIH Meeting on September 9-10, 1997 was recorded in a publicly available transcript. There, named inventor Williams gave a presentation regarding a Celgene proposal "for a distribution and education system" for thalidomide.

286. Williams stated:

> when we started in this endeavor we looked to see what else was in the marketplace that might serve as a model. We accepted that we were unlikely to find any single model that carried all of the elements that would likely be necessary for this drug, but we did find two that in part covered many of the elements that might be required. Accutane, we heard about yesterday. Comprehensive educational program, counseling, and good contraception, informed consent, a package with integrated product warnings, and a surveillance system, albeit voluntary. Many elements that clearly with either change or updating or enhancement would likely be relevant to what needed to be done for thalidomide. We also heard about the Novartis program for Clozaril, a drug used to treat schizophrenia and introduced in an era where existing antischizophrenia drugs were not particularly effective for many patients. In addition, they carried their own baggage of side effects. However, in a small proportion of patients who take this drug, a granular cytosis [sic] can develop in a very short period of time.

287. The NIH Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 patent. The NIH Transcript also qualifies as prior art to the '720, '977, and '784 Patents under 35 U.S.C. § 102(b), because it was publicly available and accessible under the Freedom of Information Act more than one year prior to the earliest priority date of the '720, '977, and '784 Patents.

288. The applicants, their agents, and/or their attorneys did not disclose the NIH Meeting or Williams' presentation at the NIH Meeting to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

289. Each of the above enumerated publications, meetings, or programs constitutes prior art that Celgene was required to, but failed to, disclose to the USPTO, for each of the Distribution Method Patents.

290. In its 2010 application for the '886 Patent, Celgene failed to disclose the existence of the PPP Package or the CDC Transcript. Had Celgene disclosed the PPP Package or the CDC Transcript, the USPTO would not have issued Celgene the '886 Patent.

11. The Distribution Method Patents are Unenforceable

291. All the above prior arts are material to the patentability of the Distribution Method Patents. They firmly establish, *prima facie*, unpatentability under 35 U.S.C. §§ 102 and 103. Each prior art listed is material to the patentability of the Distribution Method Patents because, but for Celgene's failure to disclose them, the USPTO would not have allowed any or all of the claims of the Distribution Method Patents to issue.

292. All the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they contradict or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability.

293. All of the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they constitute information that a reasonable Examiner reviewing the applications would consider material in determining whether to allow the proposed claims to issue.

294. The applicants of the Distribution Method Patents, their agents, and/or their attorneys and anyone else substantively involved in the application, owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the Distribution Method Patents issued. Pursuant to that duty, they were required to disclose all information material to the applications from which the Distribution Method Patents issued.

295. During the pendency of the applications from which the Distribution Method Patents issued, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution were aware of the above prior arts.

296. While the applications from which the Distribution Method Patents issued were pending, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution knew that the above listed prior arts were material to those applications.

297. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution withheld the above listed prior arts with the intent to deceive the Patent Examiner.

298. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution knowingly and willfully misrepresented and omitted material information during the pendency of the applications from which the Distribution Method Patents issued. But for these misrepresentations and omissions, the Distribution Method Patents would not have issued.

299. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud; accordingly, they are unenforceable.

300. The Supreme Court's decision in *Alice Corp. v. CLS Bank International*,[81] after the distribution method patents were issued, has raised doubts that REMS patents are even patentable subject matter at all. In its decision, the Court created a new test for patents that are directed to abstract ideas, such as a strategy for distribution, in which the court will examine the elements of the claim to determine whether it contains an 'inventive concept' that is enough to 'transform' the abstract idea in the claims enough to make it eligible for patent protection. Simply performing a process that has been done before, such as safely dispersing prescriptions, and performing it on a computer does not transform an abstract idea into patentable subject matter. Since *Alice,* patents for REMS distribution methods have been invalidated as unpatentable abstract ideas.[82]

301. Celgene caused the Distribution Method Patents to be listed in the Orange Book with knowledge that they were fraudulently obtained from the USPTO and are unenforceable. Celgene listed the Distribution Method Patents in the Orange Book with the intent and purpose of impeding thalidomide and lenalidomide ANDA filings and delaying FDA approval of any ANDA's for at least thirty months pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

12. Celgene Tried to Extend Its Monopoly by Filing Redundant Distribution Method Patents Based on its Previously Ill-Gotten Patents

302. Celgene applied for another patent, the '886 Patent, on December 13, 2010, just after Barr and Natco each filed an ANDA for thalidomide. Celgene's patent application did not disclose the PPP Package or the CDC Transcript as prior art.

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[81] *Alice Corp. Pty. Ltd. v. CLS Bank International, et al.,* 573 U.S. 208 (2014).
[82] *See Par Pharmaceutical, Inc., et al., v. Jazz Pharmaceuticals, Inc.,* IPR2015-00554, Paper No. 68 (P.T.A.B. July 27, 2016) for patent 7,668,730 previously held by Jazz Pharmaceuticals, https://portal.unifiedpatents.com/ptab/case/IPR2015-00554.

303. Both the PPP Package and the CDC Transcript are material to the patentability of the ’886 Patent. These two prior arts contradict or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability. They are also material because they constitute information that a reasonable Examiner would consider important in deciding whether to allow the proposed claims of the ’886 Patent to issue. Had the USPTO been aware of those undisclosed prior art references, the USPTO would not have allowed any or all of the claims of the ’886 patent to issue.

304. Celgene obtained the ’886 Patent on November 20, 2012, through knowing and willful fraud. It is therefore unenforceable. Celgene further caused the ’886 Patent to be listed in the Orange Book with knowledge that it was fraudulently obtained from the USPTO and is unenforceable. Celgene acted with the intent to thwart or otherwise discourage generic manufacturers from filing thalidomide and/or lenalidomide ANDAs, and to delay FDA approval of any such ANDA for at least thirty months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

305. The applicants of the ’886 Patent, their agents, attorneys, and anyone else substantively involved in the prosecution owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the ’886 Patent issued. As part of that duty of candor, they were required to disclose information material to the application from which the ‘886 Patent issued.

306. During the pendency of the application from which the ’886 Patent issued, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution were aware of the PPP Package and the CDC Transcript, knew that that these two prior arts were material to that application and withheld them with the intent to deceive the Patent Examiner. But for these omissions and misstatements, the ’886 Patent would not have issued.

iii. Celgene Attempted to Extend Its Monopoly by Filing Redundant Dosing Patents and Failed to Disclose Material Information on Patentability of the '745 Patent

307. Celgene filed the '745 Patent for methods and compositions for inhibition of angiogenesis in 2006, listing Robert D'Amato as inventor. D'Amato had filed and was granted the 5,593, 990 (the "'990 Patent") patent for methods and compositions for inhibition of angiogenesis in 1995, along with several other patents relating to thalidomide analogs, based on his research with The Children's Medical Center Corporation ("CMCC") in Boston. Around this same time, Celgene was beginning to file its initial patents for thalidomide analogs, which resulted in Celgene and the company to whom CMCC had licensed its patents, EntreMed, suing each other for infringement and challenging the validity of the other's patents.[83] This dispute was resolved in 2002 when the parties entered into an exclusive license agreement allowing Celgene a worldwide, exclusive license in CMCC's entire portfolio of thalidomide analog patents in exchange for paying royalties.

308. When Celgene filed for the '745 Patent and the additional dosing patents, it did not cite the '990 Patent or any of the other D'Amato dosing patents, which Celgene cannot deny they were aware of as the license holders, that dealt with treating disease states resulting from angiogenesis. The addition that anti-inflammatory drugs and NSAIDS can inhibit angiogenesis alone or in combination with thalidomide and its analogs was already disclosed by prior art. Celgene filed this redundant patent in an attempt not only to extend its monopoly but to do so in a way to not have to continue to pay royalties to CMCC. Though its attempts to maintain patent protection without paying the accompanying royalties were unsuccessful,[84] Celgene was able to

[83] *Children's Med. Center Corp. v. Celgene Corp.*, No. 13-11573, 2016 WL 3561603 (D. Mass. Feb. 23, 2016).
[84] *Children's Med. Center Corp. v. Celgene Corp.*, No. 13-11573, 2016 WL 5746358 (D. Mass. Sept. 30, 2016)

leverage the unenforceable and invalid '745 patent, as well as the additional invalid dosage patents, in its sham litigation with Lannett, discussed below. *See infra*, Part VII.e.

309. In addition to this failure to disclose, Celgene's dosing patents are invalid.

d. Celgene Filed Baseless Citizen Petitions to Stymie Generic Approval

310. As part of its multifaceted and decades long scheme to monopolize the market for Thalomid and Revlimid, Celgene filed baseless citizen petitions against generic manufacturers when manufacturers belatedly managed to secure the necessary API to file an ANDA. Celgene engaged in such anticompetitive conduct to take advantage of its knowledge that it is the standard practice for FDA to withhold ANDA approval until FDA completes its research into and response to a citizen petition. The filing of baseless citizen petitions occurred often in tangent with, and as a complement to, Celgene's sham patent litigations. *See infra*, Part VII.e.

311. To illustrate, Celgene filed a citizen petition concerning Barr's ANDA application on September 20, 2007, urging FDA not to approve Barr's thalidomide ANDA. Celgene submitted this citizen petition one year after Barr had filed its ANDA with FDA for generic Thalomid and nine months after Celgene had filed a sham patent litigation. *See infra*, Part VII.e.1. Celgene's citizen petition was baseless and intended to delay Barr's entry into the market for generic thalidomide.

312. At a meeting with Celgene in 2012, FDA's Jane Axelrad, Associate Director for Policy at CDER, commented "since 2007, Celgene's citizen's petition states there are safety concerns and this is because the company does not want generics on the market."[85] In its citizen petition, Celgene requested that FDA withhold approval of any generic thalidomide product, or alternatively: i) require the application for generic thalidomide to be subject to the same

[85] Exhibit to MSJ Opp., Doc. No. 285-15.

conditions of approval applied to Thalomid under Subpart H of 21 C.F.R. Part 314; and ii) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for, and registering patients with, multiple myeloma, in violation of Celgene's orphan drug exclusivity, which would expire in 2013.

313. Celgene's petition was meritless. It lacked any reasonable regulatory, scientific, medical, or other basis. FDA lacked statutory authority to withhold approval of generic thalidomide on the bases given by Celgene or to require the actions Celgene requested. Like its litigation against Barr, this citizen's petition was also a sham designed to maintain Celgene's monopoly.

314. On December 19, 2008, Barr responded to the petition, arguing that it "is nothing more than yet another attempt by a brand company to block all generic competition using market exclusivity protecting just a single approved indication."[86] Barr explained that Celgene's pretextual safety concerns were "hyperbole designed to improperly play on the public's fears regarding thalidomide," and that Barr's proposed thalidomide would be safe and its label would contain all precautionary information contained in the Thalomid label. Specifically, Barr argued that the law permits it to carve-out from its label Thalomid's protected MM indication, and that "Barr's Thalidomide Labeling Need Not Contain The Multiple Myeloma Indication To Ensure The Safe And Effective Use Of The ANDA Product."

315. Nearly six years later, on September 30, 2014, FDA denied Celgene's citizen petition. Specifically, FDA "den[ies] your request that FDA decline to approve any ANDA for thalidomide."

[86] Exhibit to MSJ Opp., Doc. No. 285-17.

316. Celgene's filing of baseless citizen petitions was part of, and advanced, its scheme to unlawfully monopolize the markets for Thalomid and Revlimid.

e. Celgene Serially Commenced "Sham" Patent Litigation and Struck Confidential Settlement Deals with the Generic Sponsors Which Likely Included Anticompetitive Reverse Payment Terms to Delay or Exclude Would-Be Competitors from Entering the Markets for Thalomid and Revlimid

317. In conjunction with its filing of citizen petitions against would-be competitors, Celgene also serially filed "sham" patent litigations using its fraudulently obtained patents against would-be competitors who had already been delayed by Celgene's multifaceted scheme. Furthermore, whenever dilatory litigation tactics would fail, Celgene would induce generic companies to settle, including agreements with: (1) Barr; (2) Natco, Arrow, and Watson; and (3) Alvogen and Lotus. These settlement deals likely included anticompetitive "reverse payment" terms that allowed the settling generics to share in the monopolistic profits generated by Celgene's monopolization scheme and forced BCBSA to continue to pay supracompetitive prices for Thalomid and Revlimid.

318. In 2008, Celgene filed a patent infringement lawsuit against Barr, and in 2015 against Lannett, for its thalidomide ANDAs.

319. In 2010, Celgene filed a patent lawsuit against Natco for its lenalidomide ANDA. In 2016, Celgene filed a patent lawsuit against Dr. Reddy's for its lenalidomide ANDA. In 2017, Celgene filed patent lawsuits against Zydus Pharmaceuticals ("Zydus") and against Cipla Ltd. ("Cipla") for their lenalidomide ANDAs. In 2018, Celgene filed patent lawsuits against Lotus Pharmaceuticals ("Lotus"), Sun Pharmaceutical ("Sun"), Hetero Labs Ltd. ("Hetero"), and Apotex Inc. ("Apotex"), and for its lenalidomide ANDAs.

320. In all cases, Celgene complained that the generic versions of Thalomid and Revlimid infringed Celgene's patents related to its REMS procedures of ensuring safe use of the drug. Barr, Natco, Lannett, and Dr. Reddy's each counterclaimed, alleging that Celgene's patents are invalid as prior art or for obviousness, under 35 U.S.C. §§ 102 and/or 103. Because Celgene knew that its patents were invalid, it also must have known that the litigation to enforce the invalid patents would be unsuccessful. It brought the actions only because the filing would delay generic entry into the markets.

i. Celgene's Sham Litigation Against Barr

321. Barr filed an ANDA with FDA for a generic version of Thalomid in September 2006. In its application, Barr alleged that Celgene's patents were invalid. Barr sent Paragraph IV notifications to Celgene on December 5, 15, and 19, 2006.[87]

322. As a result, Celgene filed a lawsuit against Barr in 2007,[88] and a citizen petition on September 20, 2007. The lawsuit was filed solely to take advantage of the 30-month statutory stay of FDA approval for Barr's generic thalidomide product. The patents at issue concerned the method-of-use rather than the pharmaceutical process; the patents were the result of academic conferences, and thus prone to invalidity on the grounds of obviousness. The litigation was a means to illegally prolong Celgene's monopoly.

323. In the lawsuit, Barr counterclaimed, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

324. Upon information and belief, while that action was pending, Barr predicted that its generic version of Thalomid, thalidomide capsules in 50mg, 100mg, 150mg, and 200mg,

[87] Answer and Counterclaim, *Celgene Corp. v. Barr Laboratories, Inc., et al.,* No. 2:07-cv-286, ECF No. 9, at 10 (D.N.J. Mar. 1, 2007).
[88] *Celgene Corp. v. Barr Laboratories, Inc., et al.,* No. 2:07-cv-286 (D.N.J. Jan. 18, 2007) (J. Wigenton).

would launch on the market on June 8, 2009. At the same time, it predicted filing an ANDA for its generic version of Revlimid, lenalidomide capsules, on December 27, 2009, and launching that product August 27, 2012.

325. Celgene's patent lawsuit against Barr initiated a 30-month stay of FDA approval for Barr's thalidomide ANDA pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

326. The parties engaged in discovery through spring 2010. On May 5, 2010, as part of a settlement agreement, the terms of which are confidential, Barr/Teva[89] requested FDA withdraw Barr's thalidomide ANDA. Barr/Teva withdrew its ANDA due to "lack of commercial viability" while maintaining that "we still believe Teva or another drug maker may file a paragraph IV filing for Revlimid at some point despite the potential difficulties challenging a controlled-distribution program."[90] On May 26, 2010, the court approved Barr and Celgene's stipulation of dismissal. This settlement had the anticompetitive effects of keeping Barr's generic thalidomide and generic lenalidomide off the market.

327. The settlement's terms may have included a reverse payment agreement from Celgene to Barr. A reverse payment patent settlement exists when a patent holder, here Celgene, settles a patent infringement action that the patent holder brought by making a payment to a potential competitor in consideration for its agreement to either delay or refrain from entering the patent holder's market.

328. This type of illegal and anticompetitive settlement artificially blocks competition, allowing Celgene to continue charging higher prices. When a patent holder can control an entire

[89] Teva purchased Barr in 2008.
[90] Exhibit to MSJ Opp., Doc. No. 285-17.

market through sham litigation, it can set supracompetitive prices for necessary products, leaving consumers with no choice but to pay the artificially inflated prices.

329. A reverse payment not only grants a patent holder a stranglehold on the market, but it also indicates the invalidity of the brand manufacturer's—Celgene's—patents. Celgene's patents at issue concern methods-of-use for Thalomid and Revlimid, rather than the pharmaceutical process itself. Moreover, Celgene's patents were largely based on academic and government studies and conferences and are thus prone to invalidity on the grounds of obviousness. Celgene's patent litigation was not in good faith.

330. But for the confidential settlement which may have contained illegal pay-for-delay provisions, Barr would have pursued its 2008 thalidomide ANDA, filed a generic lenalidomide ANDA, and launched both of those products in 2009 and 2012, respectively. Celgene's conduct therefore had the anticompetitive effects of delaying and indefinitely postponing the testing and introduction of generic alternatives. This has caused great expense to BCBSA, as a generic lenalidomide product has still never been brought to market.

ii. Celgene's Sham Litigation Against Lannett

331. After Celgene and Lannett reached a confidential settlement in 2011, in late 2013 Lannett announced that its BE studies were going well, and it expected to submit a thalidomide ANDA application to FDA in January 2014. In December 2014, Lannett filed ANDA No. 206601 with FDA to gain approval to market its generic version of Thalomid. Lannett also filed a Paragraph IV certification, alleging that Celgene's patents were invalid.

332. Celgene filed a patent lawsuit against Lannett in response on January 30, 2015, alleging infringement of fifteen different patents.[91] Lannett filed counterclaims against Celgene,

[91] *Celgene Corp. v. Lannett Holdings, Inc*., No. 2:15-cv-00697 (D.N.J.) (Wigenton, J.).

alleging that each and every patent at issue was invalid, was unenforceable, or was not infringed by Lannett's Paragraph IV certification.

333. Celgene's lawsuit triggered a 30-month statutory stay of FDA approval of Lannett's generic thalidomide product.[92]

334. On October 10, 2017, Celgene and Lannett stipulated to a settlement wherein Lannett would change its Paragraph IV certification on the '745 Patent to a Paragraph III certification and no longer seek FDA approval of its ANDA prior to the expiration of the '745 Patent, and Celgene would dismiss its claims of patent infringement.

335. On October 30, 2017, Lannett and Celgene announced that they entered into a settlement and license agreement related to Thalomid that would permit Lannett to manufacture and market its generic thalidomide product as of August 1, 2019. The terms of the license agreement are confidential.

336. The anticompetitive effects of Celgene's conduct were to delay Lannett's initial ANDA filing, and then to further delay FDA approval of Lannett's generic thalidomide product, and finally, to delay the entry date of Lannett's thalidomide product. There are currently no generic thalidomide products available for BCBSA to purchase for its enrollees and Lannett has since announced a target of 2021 to launch generic thalidomide.[93]

iii. Celgene's Sham Litigation Against Natco, Arrow, and Watson

337. Natco Pharma is an Indian generic prescription drug manufacturer that partnered with Arrow and Watson to produce and market a generic version of Revlimid.

338. On or about August 30, 2010, Natco sent Celgene a required notice letter of its Paragraph IV certifications, which contained a detailed factual and legal statement as to why

[92] *See* 21 U.S.C. § 355(j)(5)(B)(iii).
[93] Https://www.sec.gov/Archives/edgar/data/57725/000110465919047753/a19-12375_110k.htm.

Celgene's Distribution Method Patents, and certain patents that Celgene listed in the Orange Book in connection with NDA No. 21-880 that related to the chemical composition of Revlimid, including, the '517 Patent, 6,281,230 Patent ("'230 Patent"), 6,555,554 Patent ("'554 Patent"), 7,119,106 Patent ("'106 Patent"), and the '800 Patent, among others, are invalid, unenforceable, and/or not infringed by Natco's lenalidomide ANDA.

339. On approximately September 24, 2010, Natco filed ANDA No. 201452 seeking approval for 5 mg, 10 mg, 15mg, and 20mg lenalidomide capsules. The ANDA showed that Natco's generic lenalidomide products are bioequivalent to Celgene's Revlimid.

340. Celgene filed a patent infringement suit against Natco on October 8, 2010.[94] In November and December 2012, Celgene caused additional patents related to the chemical composition of Revlimid, patent number 8,288,415 ("'415 Patent") and the '886 Patent, respectively, to be listed in the Orange Book in connection with Revlimid.

341. On November 18, 2010, Natco filed its answer and counterclaimed that its ANDA does not infringe Celgene's relevant patents, and that Celgene's relevant patents are invalid and unenforceable.

342. On March 14, 2013, Natco sent Celgene another required notice letter of its Paragraph IV certifications, which contained a detailed factual and legal statement explaining that the '415 and '886 patents are invalid, unenforceable, and/or not infringed by Natco's lenalidomide generics.

343. On April 10, 2013, Celgene caused the '717 Patent to be listed in the Orange Book in connection with Revlimid. On April 30, 2013, the USPTO issued patent 8,431,598 ("'598 Patent") to Celgene.

[94] *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197 (D.N.J.).

344. On May 6, 2013, Celgene filed its Fifth Amended Complaint against Natco Pharma, Arrow, and Watson, claiming that Natco's lenalidomide generics would infringe the Distribution Method Patents, the '886 patent, and the '517, '230, '554, '106, '800, '415, '717, and '598 patents. The invalidity of these patents is discussed above.

345. Natco argued that the '517, '230, '554, '106, '800, '415, '717, and '589 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and/or doctrines of double patenting. Moreover, Natco argued that its lenalidomide generics do not infringe Celgene's '800 Patent as Natco's lenalidomide does not contain lenalidomide hemihydrate.

346. Celgene argued, and the court agreed, that "hemihydrate" means "a hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate."

347. Accordingly, using this definition, Celgene's '800 Patent is invalid under 35 U.S.C. § 112 for indefiniteness and lack of written description and lack of enablement.

348. Natco filed counterclaims against Celgene, alleging fraud on the USPTO, and invalid and/or unenforceable patents. Celgene's sole purpose in litigating the alleged infringement was to delay generic entry into the Revlimid market.

349. On December 22, 2015, Celgene announced that it reached a settlement with Natco. On January 4, 2016, the District Court issued a consent judgment dismissing all claims with prejudice. Under the terms of the settlement agreement, Natco Pharma, Arrow, and Watson are enjoined from marketing unlimited quantities of generic lenalidomide until January 1, 2026, one year before the expiration of the at issue patents. Starting in March 2022, Natco will be allowed to market a limited amount of generic lenalidomide. The allowed quantity will increase each year until 2026. "The volume limit is expected to be a mid-single-digit percentage of the

total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025, and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license under [the] agreement."[95] This agreement functions as a "no authorized generic" provision because it restricts Celgene's ability to launch its own generic by providing for penalties in the event an authorized generic product is launched. Additionally, the volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition. The net result of the volume restriction and agreement to not launch an authorized generic is that Celgene retains its monopoly for brand Revlimid.

350. The anticompetitive effects of Celgene's conduct were to delay Natco's ANDA and generic entry in the Revlimid market. Though Natco filed its lenalidomide ANDA in September 2010, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and BCBSA is forced to purchase brand-name Revlimid at Celgene's supracompetitive prices for its enrollees until at least 2022, and given volume limitations, likely until 2026.

iv. Celgene's Sham Litigation Against Dr. Reddy's

351. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Dr. Reddy's. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

1. Polymorphic Forms and Methods of Treatment Patents

352. On October 20, 2016, Celgene filed yet another patent infringement action, this time against Dr. Reddy's, for filing ANDA No. 209348 for various dosages of its generic

[95] https://www.sec.gov/Archives/edgar/data/816284/000157104915010171/t1503008_ex99-1.htm

alternative to Revlimid, allegedly infringing Celgene's '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and the '622 Patent.[96]

353. In its answer, filed on November 18, 2016, Dr. Reddy's claimed that all seven patents asserted were not duly and/or lawfully issued. It also counterclaimed that all seven patents were invalid and/or unenforceable. The parties filed opening Markman briefs on December 2017. On March 23, 2018, Celgene notified the court that the parties resolved their claim construction disputes and would not be filing responsive Markman briefs.

354. A settlement conference was held on January 10, 2019. Expert discovery was set to close on March 13, 2020. The case currently remains pending. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

2. Additional Methods of Treatment Patents

355. On July 20, 2017, Celgene filed suit against Dr. Reddy's for filing ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's '740 Patent, '717 Patent, and '120 Patent.[97]

356. Dr. Reddy's filed its answer on October 3, 2017 and an amended answer on October 18, 2017. Celgene filed its answer to Dr. Reddy's counterclaim on November 15, 2017.

357. A settlement conference was held on January 10, 2019. Expert discovery was set to close on March 26, 2020.

358. On March 2, 2020, the court ordered the parties to engage in confidential mediation, scheduled for April 2, 2020. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

[96] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-07704 (D.N.J.).
[97] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:17-cv-05314 (D.N.J.).

3. Methods of Delivery Patents

359. On April 12, 2018, Celgene filed suit against Dr. Reddy's for filing ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's '720 Patent, '977 Patent, '784 Patent, '886 Patent, and '531 Patent.[98]

360. Dr. Reddy's filed its answer and counterclaims on April 30, 2018 and an amended answer with counterclaims on May 31, 2018. Celgene filed its answer to Dr. Reddy's counterclaims on June 28, 2018.

361. On February 14, 2019, the parties agreed to stay the action until July 1, 2019. On July 1, 2019, the parties again agreed to stay the action through January 9, 2020, subject to renewal by the parties.

362. On March 4, 2020, the parties again agreed to stay the action until June 15, 2020. The case currently remains stayed.

363. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

v. Celgene's Sham Litigation Against Zydus

364. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Zydus that remain pending. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

1. Polymorphic Form and Methods of Treatment Patents

365. On April 12, 2017, Celgene filed a patent infringement action against Zydus and its healthcare arm, Cadila Healthcare Limited, for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly infringing Celgene's same '800 Patent, '217

[98] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:18-cv-06378 (D.N.J.).

Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[99] This combination of patents has become central to Celgene's strategy of blocking generic competitors.

366. On August 7, 2017, Zydus filed its answer and counterclaimed that each of Celgene's asserted patents are invalid, unenforceable, or noninfringed.

367. On January 14, 2019, the court ordered mediation between the parties.

368. On May 10, 2019, the court issued an Amended Scheduling Order. On December 30, 2019, the court ordered the parties to present a final schedule for the remainder of expert discovery that takes into account the age of the case.

369. On March 13, 2020, Celgene filed a motion to stay proceedings, filed under seal.

370. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

2. Additional Polymorphic Form Patents

371. On April 27, 2018, Celgene filed yet another patent infringement action against Zydus for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's 7,977,357 patent ("'357 Patent"), 8,193,219 Patent ("'219 Patent"), and '598 Patent.[100]

372. On July 9, 2018, Zydus filed its Answer.

373. On January 14, 2019, the court ordered mediation between the parties. Fact discovery closed on August 30, 2019.

374. On March 13, 2020, Celgene filed a motion to stay proceedings, filed under seal. The suit currently remains pending.

[99] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-02528 (D.N.J.).
[100] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:18-cv-08519 (D.N.J.).

375. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

vi. Celgene's Sham Litigation Against Cipla

376. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Cipla that remain pending. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

1. Polymorphic Form and Methods of Treatment Patents

377. On August 15, 2017, Celgene filed a patent infringement action, this time against Cipla, for filing ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the same combination of the '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and the '622 Patent.[101]

378. On August 16, 2018, Celgene stipulated to a dismissal of its claims regarding the '217 Patent and filed a covenant not to sue Cipla for infringement of the '217 Patent.

379. On January 14, 2019, the court ordered mediation between the parties. On February 6, 2019 the parties informed the court that Markman hearings were no longer necessary.

380. On June 4, 2019, the court ordered an amended scheduling order. On June 8, 2020, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 19-14731.

381. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

2. Additional Polymorphic Form Patents

[101] *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163 (D.N.J.).

382. On May 8, 2018, Celgene filed a patent infringement action against Cipla for filing its ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene alleged would also infringe the same combination of the '357 Patent, '219 Patent, and the '598 Patent.[102]

383. On July 16, 2018, Cipla filed its answer and counterclaims. On August 20, 2018, Celgene filed its answer to Cipla's counterclaim.

384. On April 30, 2019, the court issued a stipulated order in which the parties agreed not to contest a finding that products derived from Cipla's ANDA would infringe Celgene's patents at issue. On June 8, 2020, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 19-14731.

385. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

3. Additional Litigation

386. On July 3, 2019, Celgene filed another patent infringement action against Cipla for filing its ANDA No. 213165 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the '800 Patent, the '217 Patent, the '569 Patent, the '498 Patent, the '095 Patent, the '621 Patent, the '622 Patent, the '740 Patent, the '717 Patent, and the '120 Patent.[103]

387. On August 26, 2019, Cipla filed its answer and counterclaims, alleging that the patents at issue were all invalid, unenforceable, or would not be infringed by activity described

[102] *Celgene Corp. v. Cipla Ltd.*, No. 2:18-cv-08964 (D.N.J.).
[103] *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J.).

in Cipla's Paragraph IV certification for ANDA No. 213165. On October 18, 2019, Celgene filed its answer to Cipla's counterclaim.

388. On May 28, 2020, Celgene filed its First Amended Complaint, alleging that Cipla's ANDA would infringe every patent at issue in the two prior suits filed against Cipla.[104] The case remains pending.

389. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

vii. Celgene's Sham Litigation Against Alvogen and Lotus

390. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Lotus and Alvogen, Inc. ("Alvogen"). It brought the actions only because the filing would delay generic entry into the lenalidomide market.

1. Polymorphic Form, Distribution Method, and Methods of Treatment Patents

391. On September 6, 2017, Celgene filed a patent infringement action against Lotus and Alvogen for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '517 Patent, '720 Patent, '977 Patent, '784 Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent.[105]

392. On October 5, 2017, Lotus and Alvogen filed its answer and counterclaims, seeking declaratory judgments that the patents at issue were all invalid, unenforceable, or would not be infringed by activity described in Lotus and Alvogen's Paragraph IV Certification.

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[104] First Amended Complaint, *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731, ECF No. 64 (D.N.J.).

[105] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842 (D.N.J.).

393. On March 29, 2019, Celgene, Lotus, and Alvogen stipulated and consented to an entry of judgment and an injunction prohibiting Lotus and Alvogen from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above. Alvogen agreed not to litigate the validity of Celgene's patents for Revlimid in exchange for some volume-limited entry, similar to that reached with Natco described above.[106] This "volume limited" generic entry settlement agreement similarly protected the Revlimid monopoly by protecting Celgene's brand Revlimid sales from generic competition.

394. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that may include illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

2. Additional Polymorphic Form Patents

395. On July 10, 2018, Celgene filed a patent infringement action against Lotus and Alvogen for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would also infringe its '357 Patent, '219 Patent, and the '598 Patent.[107] The patents that Celgene has claimed would be infringed in this case, however, have not been submitted to the Orange Book by Celgene in association with Revlimid as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. Celgene was required to list with its NDA, or within thirty days for a new patent after the NDA has been submitted, any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its drug. By citing these patents that were not filed in the Orange Book,

[106] https://ir.celgene.com/press-releases-archive/press-release-details/2019/Celgene-Settles-US-REVLIMID-Patent-Litigation-with-Alvogen/default.aspx
[107] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al*, No. 2:18-cv-11518 (D.N.J.).

Celgene is either filing a frivolous infringement claim for a patent that it does not believe could be reasonably asserted or failing to list patents properly which could give rise to administrative action or potentially additional antitrust liability if done in an attempt to delay filing and further extend its monopoly.

396. On March 29, 2019, Celgene, Lotus, and Alvogen stipulated and consented to an entry of judgment and an injunction prohibiting Lotus and Alvogen from marketing and selling its generic lenalidomide until the expiration of the patents-in-suit listed above.

397. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that may include illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

viii. Celgene's Sham Litigation Against Sun

398. In Spring 2018, Sun filed ANDA No. 211846 for generic lenalidomide. On May 30, 2018, Sun sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Sun's ANDA.

399. On July 13, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Sun Pharmaceuticals Industries Inc. and related entities for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, and its '569 Patent.[108]

400. On August 14, 2018, Sun filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

401. On November 21, 2019, the court issued an amended scheduling order.

[108] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:18-cv-11630 (D.N.J.).

402. On December 12, 2019, the court cancelled Markman hearings upon the parties' joint motion. The case is currently pending.

403. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

ix. Celgene's Sham Litigation Against Hetero

404. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Hetero. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

1. Polymorphic Forms and Methods of Treatment Patents

405. In fall 2018, Hetero filed its ANDA for generic lenalidomide. On November 9, 2018, Hetero sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Hetero's ANDA.

406. On December 20, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Hetero Labs Ltd.[109] for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[110]

407. On March 11, 2019, Hetero filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. On April 15, 2019, Celgene filed its answer to Hetero's counterclaim.

[109] The complaint also named Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero").
[110] *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2:18-cv-17463 (D.N.J.).

408. On January 21, 2020, the District Court entered a stipulation dismissing without prejudice the claims relating to the '217 Patent, '363 Patent, and the '929 Patent. The case is currently pending.

409. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

2. Additional Methods of Treatment Patents

410. On July 16, 2019, Celgene filed yet another patent infringement action against Hetero for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would also infringe its '740 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent.[111]

411. On October 11, 2019, Hetero filed its answer and counterclaims against Celgene, for which Celgene filed an answer on November 15, 2019.

412. On December 18, 2019, the court issued a pretrial scheduling order. The case remains pending.

413. The anticompetitive effect of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

x. Celgene's Sham Litigation Against Apotex

414. In winter 2017, Apotex filed its ANDA for generic lenalidomide. On November 28, 2017, Apotex sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Apotex's ANDA.

415. On January 11, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Apotex for filing ANDA No. 211022 for various

[111] *Celgene Corp. Hetero Labs Ltd., et al.*, No. 2:19-cv-15449 (D.N.J.).

dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '720 Patent, '977 Patent, '784 Patent, '886 Patent, '531 Patent, '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[112]

416. On August 30, 2018, Apotex filed its answer and affirmative defenses, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. Apotex alleged that five of the patents-in-suit are unenforceable due to patent misuse because Celgene asserted the patents even though no reasonable litigant could believe they were valid in light of prior proceedings in front of the PTAB.

417. On April 30, 2019, the District Court issued a consent judgment that the '217 Patent was not infringed by ANDA No. 211022.

418. On May 8, 2019, the District Court issued an order bifurcating the claims and staying the action as to the '720 Patent, '977 Patent, '784 Patent, '886 Patent, and the '531 Patent.

419. The case is currently pending as to claims concerning the '800 Patent, '363 Patent, and the '929 Patent.

420. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

VIII. CELGENE INTENDED TO AND DID HARM COMPETITION

421. Celgene's scheme was intended to and did in fact block and delay generic thalidomide and lenalidomide entry into the market, disrupted the normal distribution channels, and manipulated the statutory and regulatory mechanisms by which generic competition takes

[112] *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461 (D.N.J.).

place, and otherwise excluded generic competitors from efficiently marketing and distributing their products.

422. But for Celgene's anticompetitive scheme, generic Thalomid would have been brought to market possibly at least as early as spring 2009. Celgene illegally prevented competitors, including Mylan in 2004, Barr in 2005, and Lannett in 2007, from obtaining Thalomid samples for bioequivalence testing. When Barr filed an ANDA in September 2005, Celgene executed a contract with Barr's API supplier that contained an anticompetitive exclusive dealing provision that created deficiencies in Barr's ANDA application and required Barr to undergo new bio-studies and validation testing, delaying Barr's ANDA one year. When Barr filed its ANDA in September 2006, Celgene filed a sham litigation suit to enforce its invalid and unenforceable patents. The litigation was halted when Celgene and Barr reached a confidential settlement which resulted in a continued absence of generic Thalomid from the market.

423. But for Celgene's anticompetitive conduct, generic Revlimid would have entered the market in 2010 or soon thereafter. Celgene once again prevented multiple competitors including Mylan, Natco Pharma, Dr. Reddy's, Teva, and Watson from obtaining Revlimid from Celgene for BE testing. Celgene refused to supply samples to Mylan, and Mylan has been unable to complete BE testing or file an ANDA for lenalidomide. Natco filed its lenalidomide ANDA in September 2010 and would have brought generic Revlimid to market shortly thereafter, but for Celgene's sham patent infringement lawsuit and the subsequent settlement wherein Natco agreed not to sell generic lenalidomide until 2022, in limited quantities. Dr. Reddy's filed its lenalidomide ANDA in 2016, after which Celgene once again filed a sham patent litigation which is still pending. Lannett filed its thalidomide ANDA in December 2014, after which Celgene filed a sham patent litigation that resulted in a settlement wherein Lannett's thalidomide

could not be sold until August 2019. Zydus, Cipla, Lotus, Hetero, Apotex, and Sun each filed lenalidomide ANDAs and were met with Celgene's serial sham litigation tactic, delaying the entry of their generic Revlimid products into the market.

424. All of Celgene's patents on Revlimid are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or doctrines of double-patenting.

425. Celgene's unjustifiable refusal to cooperate with the generic ANDA filers directly prevented generic filers from obtaining FDA approval. But for Celgene's unlawful conduct, FDA would have given final approval to the pending generic manufacturer's ANDAs and allowed them to enter the market.

426. Celgene cannot justify its scheme by pointing to any consumer benefit. Generic drugs offer enormous cost savings, which outweigh any non-pretextual, if there even are any, justifications Celgene could possibly offer.

IX. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID CAUSED BCBSA TO PAY MORE THAN IT WOULD HAVE PAID IN AN UNMANIPULATED MARKET

427. Celgene's scheme suppressed the ability of generic Thalomid and Revlimid substitutes to compete in the market under the governing statutory and regulatory scheme.

428. The absence of generic competition injured BCBSA because it would have paid less for Thalomid and Revlimid, or their generic alternatives, by substituting purchases of less expensive AB-rated generic drugs for their purchases of more expensive branded drugs, receiving discounts on their remaining purchases of branded drugs, and by purchasing generic versions of Thalomid and Revlimid at lower prices sooner.

429. As a result, BCBSA has sustained substantial losses and damages to its business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

X. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID AFFECTED INTERSTATE COMMERCE FOR THOSE DRUGS

430. At all material times, Thalomid and Revlimid, manufactured and sold by Celgene, were shipped across state lines and sold to customers located outside of its state of manufacture.

431. Between at least 2010 and the present, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

432. At all material times, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Celgene as charged were within the flow of, and have substantially affected interstate commerce, money, contracts, and bills, and other forms of business communications were transmitted in a continuous and uninterrupted flow across state lines.

XI. CELGENE MAINTAINED MONOPOLY MARKET POWER OVER THALOMID AND REVLIMID AND THEIR GENERIC FORMS

433. At all relevant times, Celgene has had power over the market for Thalomid and Revlimid in all their forms and dosages, which are still only available in the form of branded Thalomid and branded Revlimid. Celgene has and continues to have the power to maintain and increase the price of Thalomid and Revlimid to supracompetitive levels without losing sales, because Celgene has successfully conspired to keep AB-rated generic versions of Thalomid and Revlimid from reaching the U.S. market at all.

434. A small, but significant, non-transitory price increase for Thalomid or Revlimid by Celgene would not have caused a significant loss of sales.

435. Celgene needed to control only Thalomid and Revlimid and their AB-rated generic equivalents, and no other products, to maintain the price of Thalomid and Revlimid at supracompetitive prices. Only the market entry of a competing AB-rated generic version of those drugs would render Celgene unable to maintain its market monopoly.

436. If BCBSA is legally required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant market for Thalomid is all dosages of thalidomide, *i.e.*, Thalomid and its AB-rated generic equivalents, and for Revlimid is all dosages of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents.

437. Thalomid and Revlimid do not exhibit significant, positive cross-elasticity of demand regarding price with any other product, due to FDA regulatory hurdles incident to securing an AB rating and laws allowing pharmacists to substitute only AB-rated generics for prescribed branded drugs.

438. There are no interchangeable drug products available for purchasers of Thalomid and Revlimid.

439. Celgene needed to control the output of Thalomid and Revlimid and its AB-rated generic equivalents only, and no other products, to maintain the price of Thalomid and Revlimid profitably at supracompetitive prices. Only the market entry of a competing AB-rated generic version of Thalomid or Revlimid would render Celgene unable to profitably maintain its current prices of those drugs without losing substantial sales.

440. Celgene also sold branded Thalomid and Revlimid well over marginal costs, and substantially more than the competitive price, and enjoyed unusually high profit margins.

441. Celgene has had, and so exercised, the power to exclude and restrict competition for Thalomid and Revlimid.

442. Without the power to exclude and restrict competition for Thalomid and Revlimid, and the ability to sell its own branded version of those drugs at prices well over marginal costs, it would not have been economically rational for Celgene to pay Natco, and potentially other generic manufacturers, unusually exorbitant settlement payments to delay the launch of generic Thalomid and Revlimid.

443. At all relevant times, Celgene has enjoyed the benefits of high barriers to entry with respect to competition to the above-defined market due to patent and other regulatory protections.

444. The relevant geographic markets are (i) the United States and its territories, and (ii) each of the states in which BCBSA members purchased Thalomid and/or Revlimid and under whose laws BCBSA asserts claims for relief. At all relevant times, Celgene's market share in the relevant market was, and continues to be, 100%.

XII. ANTITRUST INJURY

445. Celgene's use of the regulatory process as an anticompetitive tool to block and delay generic competition for Thalomid and Revlimid keeps costs high for insurers like BCBSA.

446. BCBSA paid substantial sums to purchase Thalomid and Revlimid during the relevant times and its members paid additional sums in cost-sharing for Thalomid and Revlimid. Because of Celgene's illegal conduct, BCBSA has been compelled to pay artificially inflated prices for Thalomid and Revlimid. Those prices have been substantially higher than the prices that BCBSA would have paid for generic Thalomid and generic Revlimid but for the illegal conduct alleged. BCBSA and its members continue to pay artificially high, supracompetitive prices for Thalomid and Revlimid.

447. Consequently, BCBSA, a purchaser of Thalomid and Revlimid, has sustained substantial losses and damage to its business and property in the form of overcharges. The full

amount, forms, and components of such damages will be determined after discovery and upon proof at trial.

448. Celgene's efforts to restrain competition in the defined relevant markets has and continues to substantially affect interstate and intrastate commerce throughout the United States.

449. Excluding generic competitors prevented price competition for Thalomid and Revlimid.

450. Prices for Thalomid and Revlimid have been and will continue to be inflated as a direct and foreseeable result of Celgene's anticompetitive conduct. The inflated prices that BCBSA has paid and will continue to pay are traceable to, and the foreseeable result of, the overcharges by Celgene.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Sections 2 and 3 of the Sherman Act

451. BCBSA incorporates by reference the preceding allegations.

452. Celgene knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Thalomid and Revlimid. Celgene injured BCBSA through this conduct.

453. Had manufacturers of generic Revlimid and generic Thalomid entered the market and lawfully competed with Celgene, BCBSA would have substituted lower-priced generic Revlimid and generic Thalomid for the higher-priced brand-name drugs for most purchases.

454. BCBSA has suffered harm and will continue to suffer harm in the future as a result of paying higher prices for Thalomid and Revlimid than it would have absent Celgene's continuing anticompetitive conduct.

455. BCBSA's allegations described herein and in claims II through V comprise violations of Sections 2 and 3 of the Sherman Act, as well as state laws.

456. BCBSA has purchased substantial amounts of Thalomid and Revlimid from at least 2010 through the present.

457. BCBSA seeks a declaratory judgment under Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) ruling that Celgene's conduct violates Sections 2 and 3 of the Sherman Act.

458. BCBSA also seeks equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Celgene's unlawful conduct and other relief to assure that similar anticompetitive conduct does not recur.

459. BCBSA has no adequate alternative form of relief in the United States for its overpayment for Thalomid and Revlimid purchased indirectly in the states that do not provide damages remedies to indirect purchasers injured by Celgene's anticompetitive agreement.

SECOND CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law

460. BCBSA incorporates by reference the preceding allegations.

461. Celgene possessed monopoly power in the defined relevant market at all times since its NDAs for Thalomid and Revlimid were respectively approved. Celgene knowingly and willfully engaged in a course of exclusionary conduct designed to prevent generic manufacturers from entering the market and unlawfully extended its monopoly power.

462. Celgene intentionally extended its monopoly power in the relevant market through its anticompetitive and illegal scheme. Thus, BCBSA paid artificially inflated prices for

its purchases of Thalomid and Revlimid. There is and was no non-pretextual justification for Celgene's anticompetitive actions.

463. As a direct and proximate result of Celgene's conduct, as alleged herein, BCBSA was injured.

464. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases of Thalomid and Revlimid in Arizona.

b. Cal. Bus. & Prof. Code §§ 17200, et seq., and California common law, with respect to purchases of Thalomid and Revlimid in California.

c. Conn. Gen. Stat. §§ 35-27, et seq., with respect to purchases of Thalomid and Revlimid in Connecticut.

d. D.C. Code §§ 28-4503, et seq., with respect to purchases of Thalomid and Revlimid in the District of Columbia.

e. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Thalomid and Revlimid in Florida.

f. Hawaii Code §§ 480, et seq., with respect to purchases of Thalomid and Revlimid in Hawaii.

g. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Thalomid and Revlimid in Illinois.

h. Iowa Code §§ 553.5 et seq., with respect to purchases of Thalomid and Revlimid in Iowa.

i. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of Thalomid and Revlimid in Massachusetts by Plaintiff, who paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Massachusetts.

j. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases of Thalomid and Revlimid in Maine.

k. Md. Code, Com. Law §§ 11-204, et seq., with respect to purchases of Thalomid and Revlimid in Maryland.

l. Mich. Comp. Laws Ann. §§ 445.773, et seq., with respect to purchases of Thalomid and Revlimid in Michigan.

m. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Thalomid and Revlimid in Minnesota.

n. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases of Thalomid and Revlimid in Mississippi.

o. Neb. Code Ann. §§ 59-802, et seq., with respect to purchases of Thalomid and Revlimid in Nebraska.

p. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Thalomid and Revlimid in Nevada by Plaintiff, who paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Nevada.

q. N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases of Thalomid and Revlimid in New Hampshire.

r. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases of Thalomid and Revlimid in New Mexico.

s. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases of Thalomid and Revlimid in North Carolina.

t. N.D. Cent. Code §§ 51-08.1-03, et seq., with respect to purchases of Thalomid and Revlimid in North Dakota.

u. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of Thalomid and Revlimid in Oregon.

v. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of Thalomid and Revlimid in Puerto Rico.

w. R.I. Gen. Laws §§ 6-36-1, et seq., with respect to purchases of Thalomid and Revlimid in Rhode Island.

x. S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to purchases of Thalomid and Revlimid in South Dakota.

y. Utah Code Ann. §§ 76-10-911, et seq., with respect to purchases of Thalomid and Revlimid in Utah.

z. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases of Thalomid and Revlimid in Vermont.

aa. W.Va. Code §§ 47-18-4, et seq., with respect to purchases of Thalomid and Revlimid in West Virginia.

bb. Wis. Stat. §§ 133.03, et seq., with respect to purchases of Thalomid and Revlimid in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin,

whereby Plaintiff paid substantially higher prices for Thalomid and Revlimid at Wisconsin pharmacies.

THIRD CLAIM FOR RELIEF
Attempted Monopolization Under State Law

465. BCBSA incorporates by reference the preceding allegations.

466. Celgene, through its anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Celgene's conscious objective to control prices and exclude competition in the relevant market.

467. The natural, intended, and foreseeable consequences of Celgene's anticompetitive scheme was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

468. There is a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

469. As a direct and proximate result of Celgene's conduct, BCBSA was harmed with respect to its purchases of Thalomid and Revlimid.

470. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases of Thalomid and Revlimid in Arizona.

b. Cal. Bus. & Prof. Code §§ 17200, et seq., and California common law, with respect to purchases of Thalomid and Revlimid in California.

c. Conn. Gen. Stat. §§ 35-27, et seq., with respect to purchases of Thalomid and Revlimid in Connecticut.

d. D.C. Code §§ 28-4503, et seq., with respect to purchases of Thalomid and Revlimid in the District of Columbia.

e. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Thalomid and Revlimid in Florida.

f. Hawaii Code §§ 480, et seq., with respect to purchases of Thalomid and Revlimid in Hawaii.

g. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Thalomid and Revlimid in Illinois.

h. Iowa Code §§ 553.5 et seq., with respect to purchases of Thalomid and Revlimid in Iowa.

i. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases of Thalomid and Revlimid in Maine.

j. Md. Code, Com. Law §§ 11-204, et seq., with respect to purchases of Thalomid and Revlimid in Maryland.

k. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of Thalomid and Revlimid in Massachusetts by Plaintiff, who paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Massachusetts.

l. Mich. Comp. Laws Ann. §§ 445.773, et seq., with respect to purchases of Thalomid and Revlimid in Michigan.

m. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Thalomid and Revlimid in Minnesota.

n. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases of Thalomid and Revlimid in Mississippi.

o. Neb. Code Ann. §§ 59-802, et seq., with respect to purchases of Thalomid and Revlimid in Nebraska.

p. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Thalomid and Revlimid in Nevada by Plaintiff, who paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Nevada.

q. N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases of Thalomid and Revlimid in New Hampshire.

r. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases of Thalomid and Revlimid in New Mexico.

s. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of Thalomid and Revlimid in New York.

t. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases of Thalomid and Revlimid in North Carolina.

u. N.D. Cent. Code §§ 51-08.1-03, et seq., with respect to purchases of Thalomid and Revlimid in North Dakota.

v. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of Thalomid and Revlimid in Oregon.

w. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of Thalomid and Revlimid in Puerto Rico.

x. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases of Thalomid and Revlimid in Rhode Island.

y. S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to purchases of Thalomid and Revlimid in South Dakota.

z. Utah Code Ann. §§ 76-10-911, et seq., with respect to purchases of Thalomid and Revlimid in Utah.

aa. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases of Thalomid and Revlimid in Vermont.

bb. W.Va. Code §§ 47-18-4, et seq., with respect to purchases of Thalomid and Revlimid in West Virginia.

cc. Wis. Stat. §§ 133.03, et seq., with respect to purchases of Thalomid and Revlimid in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid substantially higher prices for Thalomid and Revlimid at Wisconsin pharmacies.

FOURTH CLAIM FOR RELIEF
Unfair and Deceptive Trade Practices Under State Law

471. BCBSA incorporates by reference the preceding allegations.

472. Celgene engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Celgene's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, BCBSA was deprived of the opportunity to purchase generic versions of Thalomid and Revlimid and forced to pay artificially inflated prices for these drugs.

473. There was and is a gross disparity between the price that BCBSA paid and continues to pay for its purchases of Thalomid and Revlimid and the value received, given that a much cheaper substitute generic product should be available, and prices for Thalomid and Revlimid should be much lower, but for Celgene's unlawful scheme.

474. By engaging in the foregoing conduct, Celgene has engaged in in unfair competition or deceptive acts and practices in violation of the following state laws:

a. Ark. Code §§ 4-88-101, et seq., with respect to purchases of Thalomid and Revlimid in Arkansas.

b. Ariz. Code §§ 44-1522, et seq., with respect to purchases of Thalomid and Revlimid in Arizona.

c. Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases of Thalomid and Revlimid in California.

d. Colo. Rev. Stat § 6-1-105, et seq., with respect to purchases of Thalomid and Revlimid in Colorado.

e. D.C. Code §§ 28-3901, et seq., with respect to the purchases of Thalomid and Revlimid in the District of Columbia.

f. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Thalomid and Revlimid in Florida.

g. Idaho Code §§ 48-601, et seq., with respect to the purchases of Thalomid and Revlimid in Idaho.

h. 815 ILCS §§ 505/1, et seq., with respect to the purchases of Thalomid and Revlimid in Illinois.

i. Ind. Code §§ 24-5-0.5-1, et seq., with respect to the purchases of Thalomid and Revlimid in Indiana.

j. Kan. Stat. §§ 50-623, et seq., with respect to the purchases of Thalomid and Revlimid in Kansas.

k. La. Rev. Stat. Ann. § 51:1401, et seq., with respect to the purchases of Thalomid and Revlimid in Louisiana.

l. 5 Me. Rev. Stat. §§ 207, et seq., with respect to the purchases of Thalomid and Revlimid in Maine.

m. Mass. Ann. Laws ch. 93A, et seq., with respect to purchases of Thalomid and Revlimid in Massachusetts.

n. Mich. Stat. §§ 445.901, et seq., with respect to purchases of Thalomid and Revlimid in Michigan.

o. Minn. Stat. § 325D.43, et. seq., Minn. Stat. § 325F.69, *et seq*., and Minn. Stat. § 8.31, et seq., with respect to purchases of Thalomid and Revlimid in Minnesota.

p. Miss. Code. Ann. § 75-24-1, et seq., with respect to purchases of Thalomid and Revlimid in Mississippi.

q. Missouri Stat. §§ 407.010, et seq., with respect to purchases of Thalomid and Revlimid in Missouri.

r. Neb. Rev. Stat. §§ 59-1601, et seq., with respect to purchases of Thalomid and Revlimid in Nebraska.

s. Nev. Rev. Stat. §§ 598.0903, et seq., with respect to purchases of Thalomid and Revlimid in Nevada.

t. N.H. Rev. Stat. §§ 358-A:1, et seq., with respect to purchases of Thalomid and Revlimid in New Hampshire.

u. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases of Thalomid and Revlimid in New Mexico.

v. N.Y. Gen. Bus. Law §§ 349, et seq., with respect to purchases of Thalomid and Revlimid in New York.

w. N.C. Gen. Stat. §§ 75-1.1, et seq., with respect to purchases of Thalomid and Revlimid in North Carolina.

x. N.D. Cent. Code § 51-15-01, et seq., with respect to purchases of Thalomid and Revlimid in North Dakota.

y. Or. Rev. Stat. §§ 646.605, et seq., with respect to purchases of Thalomid and Revlimid in Oregon.

z. 73 Pa. Stat. Ann. §§ 201-1, et seq., with respect to purchases of Thalomid and Revlimid in Pennsylvania.

aa. S.C. Stat. Ann. § 39-5-10, et seq., for purchases of Thalomid and Revlimid in South Carolina.

bb. S.D. Code Laws §§ 37-24-1, et seq., with respect to purchases of Thalomid and Revlimid in South Dakota.

cc. Utah Code §§ 13-11-1, et seq., with respect to purchases of Thalomid and Revlimid in Utah.

dd. 9 Vt. § 2451, et seq., with respect to purchases of Thalomid and Revlimid in Vermont.

ee. Va. Code Ann. §§ 59.1-196, et seq., with respect to purchases of Thalomid and Revlimid in Virginia.

ff. W.Va. Code §§ 46A-6-101, et seq., with respect to purchases of Thalomid and Revlimid in West Virginia.

gg. Wis. Stat. § 100.18; Wis. Stat. § 100.20, et. seq., with respect to purchases of Thalomid and Revlimid in Wisconsin.

hh. Wyo. Stat. Ann. § 40-12-101, et seq., with respect to purchases of Thalomid and Revlimid in Wyoming.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law

475. BCBSA incorporates by reference the preceding allegations.

476. Celgene has benefitted from monopoly profits on the sale of Thalomid and Revlimid resulting from the unlawful and inequitable acts alleged in this Complaint.

477. Celgene's financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for purchases of Thalomid and Revlimid by BCBSA.

478. BCBSA has conferred upon Celgene an economic benefit, profits from unlawful overcharges and monopoly profits, to the economic detriment of BCBSA.

479. It would be futile for BCBSA to seek a remedy from any party with whom it has privity of contract with for its purchases of Thalomid and Revlimid.

480. It would be futile for BCBSA to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which BCBSA purchased Thalomid and Revlimid, as they are not liable and would not compensate BCBSA for unlawful conduct caused by Celgene.

481. The economic benefit of overcharges and monopoly profits derived by Celgene through charging supracompetitive and artificially inflated prices for Thalomid and Revlimid is a direct and proximate result of Celgene's unlawful conduct.

482. The economic benefits derived by Celgene rightfully belong to BCBSA, as it paid anticompetitive and monopolistic prices beginning in at least 2010 and continuing through the present, and it will continue to do so until the effects of Celgene's illegal and anticompetitive conduct cease.

483. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Celgene to be permitted to retain any of the overcharges for Thalomid and Revlimid derived from Celgene's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

484. Celgene is aware of and appreciates the benefits bestowed upon it by BCBSA.

485. Celgene should be compelled to disgorge in a common fund for the benefit of BCBSA all unlawful or inequitable proceeds it received.

486. A constructive trust should be imposed upon all unlawful or inequitable sums received by Celgene traceable to BCBSA.

XIV. DEMAND FOR JUDGMENT

WHEREFORE, BCBSA demands judgment against Celgene, as follows:

487. Awarding BCBSA actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post- judgment interest at the statutory rates;

488. Awarding BCBSA equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Celgene's unjust enrichment.

489. Permanently enjoining Celgene pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 (a) and 26, from continuing its unlawful conduct;

490. Declaring the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

491. Awarding BCBSA its reasonable costs and expenses, including attorneys' fees; and

492. Awarding all other legal or equitable relief as the Court deems just and proper.

XV. JURY DEMAND

BCBSA demands a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38(b).

Dated: July 21, 2020

Respectfully submitted:

By: 

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